2015-1504

United States Court of Appeals for the Federal Circuit

TRIREME MEDICAL, LLC,

Plaintiff-Appellant,

v.

ANGIOSCORE, INC.,

Defendant-Appellee.

Appeal from The United States District Court for the Northern District Of California in Case No. 3:14-cv-02946-LB. Judge Laurel Beeler

OPENING BRIEF FOR APPELLANT

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MAY 29, 2015

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant certifies the following:

1. The full name of every party or *amicus* represented by me is:

   TriReme Medical, LLC.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   The party named in the caption is the real party in interest.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   QT Vascular Ltd.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this Court are:

   Arnold & Porter LLP: David A. Caine, James C. Otteson, Thomas T. Carmack, Michael D.K. Nguyen; Agility IP Law, LLP: David A. Caine, James C. Otteson, Brandon D. Baum, Thomas T. Carmack, Michael D.K. Nguyen

DATED: May 29, 2015

Respectfully,

By */s/ David A. Caine*
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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rules 28(a)(4) and 47.5, counsel for Plaintiff-Appellant TriReme states: (a) no other appeal in or from the same civil action in the trial court was previously before this or any other appellate court; and (b) no other case known to counsel to be pending in this or any other court will directly affect or be directly affected by this Court's decision in this appeal.

JURISDICTIONAL STATEMENT

The district court had subject matter jurisdiction under 28 U.S.C. § 1331 and § 1338(a). On March 17, 2015, the district court entered an Order dismissing Plaintiff-Appellant's claims. On April 1, 2015, the district court entered Judgment pursuant to its March 17, 2015 Order. The district court's March 17, 2015 Order and April 1, 2015 Judgment are final and disposed of all parties' claims in that action.

On March 20, 2015, Plaintiff-Appellant timely filed a Notice of Appeal, pursuant to Federal Rule of Appellate Procedure 4. This Court has appellate jurisdiction under 28 U.S.C. § 1295.

STATEMENT OF THE ISSUE

Did the district court err in finding that a consulting agreement operated to assign all of the consultant's rights to an invention that was conceived prior to the

agreement's effective date thereby depriving the consultant's licensee of standing to pursue claims for correction of inventorship even though the consultant did not participate in conception, development, or reduction to practice on or after the effective date?

STATEMENT OF THE CASE

On June 25, 2014, TriReme brought suit against AngioScore in the U.S. District Court for the Northern District of California seeking correction of inventorship pursuant to 35 U.S.C. § 256. A139-45. TriReme's complaint alleged the failure to add a co-inventor, Dr. Chaim Lotan, to three patents assigned to AngioScore. *Id*. Dr. Lotan granted TriReme an exclusive license to his inventive contribution prior to the filing of the complaint in 2014. A317-32.

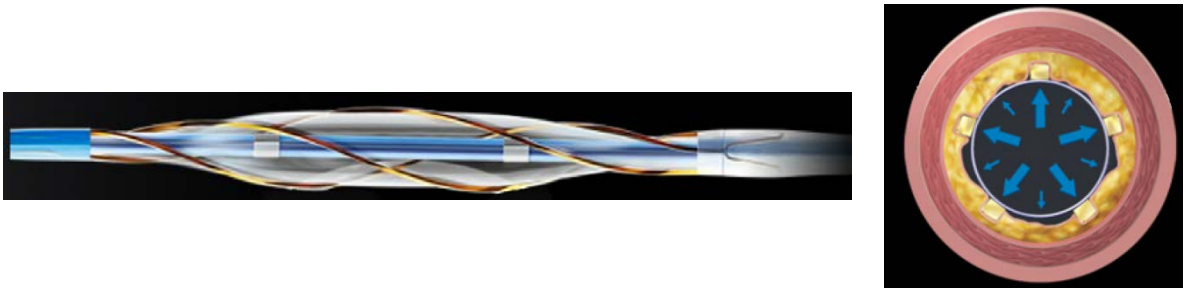
Pursuant to AngioScore's request, the District Court set a phased schedule in order to allow AngioScore to move for dismissal based on lack of standing. A221-22. An animal study report, other contemporaneous documents and Dr. Lotan's testimony establish that Dr. Lotan contributed to the conception of inventions claimed in the three patents-in-suit in April 2003. After deposing Dr. Lotan, AngioScore moved to dismiss, contending that subject matter jurisdiction did not exist because Dr. Lotan had allegedly assigned the rights in his inventive contribution to AngioScore under a May 2003 consulting agreement (the "May

2003 Agreement," A309-15) and that he, therefore, had no rights to assign to TriReme. A278-305. The District Court granted AngioScore's motion and dismissed the action with prejudice on March 17, 2015. A2-17.

STATEMENT OF FACTS

A. Dr. Lotan's Role in AngioScore's Founding and Original Patent Applications.

AngioScore sells a line of angioplasty balloon catheters under the name "AngioSculpt® Scoring Balloon Catheter." A931-32, A947-48. AngioSculpt is an angioplasty device used to open arterial blockages. To accomplish this, the balloon catheter is inserted into the vessel and extended to the site of the occlusion and is then expanded. It is called a "scoring" balloon because the balloon's expansion causes a metal spiral on the surface of the balloon to be pressed into the plaque and/or vessel. This results in the scoring or cutting of plaque to allow the vessel to expand and blood flow to increase. After the balloon is inflated, and the vessel scored, the device is removed. *Id*. An illustration of the current product from AngioScore's website is reproduced below (A947-48):



Development of the current AngioSculpt product began in 2002, before AngioScore's founding, when Dr. Eitan Konstantino—one of the founders of both AngioScore and TriReme—had the idea of using scoring elements on top of a traditional angioplasty balloon catheter. A475, 16:1-11; A704, ¶¶ 2-4. Dr. Konstantino took his idea to Mr. Tanhum Feld, a mechanical engineer with whom he had worked previously, and Dr. Chaim Lotan, a noted interventional cardiologist. *Id*; A479-80, 20:24-21:6; A506-07, 55:22-56:4; A553.

Chaim Lotan is a medical doctor living in Jerusalem, Israel, who specializes in interventional cardiology. A140-41, ¶ 8; A467, 8:9-13. Since the 1980s, he has been resident at Hadassah Medical Center where, in addition to his cardiology practice, he is the chairperson of the hospital's Heart Institute. A140-41, ¶ 8; A476-78, 17:13-19, 18:25-19:7; A548. In addition to his work at Hadassah, Dr. Lotan has held various positions in government and medical societies throughout the years. Complaint ¶ 8. He has also served on the advisory boards of several U.S. companies, including AngioScore and Medtronic. A468, 9:2-8. Through his consultation with private companies, Dr. Lotan has participated in the design, testing and regulatory approval processes for various medical devices related to interventional cardiology. *See, e.g.*, A525, 90:17-24; A475, 16:1-5.

Dr. Lotan met Dr. Konstantino in the 1990s in Israel, and was so impressed with him that he made introductions that helped Dr. Konstantino secure a position as CEO at a U.S.-based medical device company called Advanced Stent Technologies ("AST"). A473, 14:13-15:25; A704, ¶¶ 2-3. It was on a visit to the U.S. in late 2002 when Dr. Lotan first had a discussion one evening in Dr. Konstantino's home about ideas for a new "scoring device." A475, at 16:1-11; A704, ¶ 3.

Drs. Lotan and Konstantino pursued the scoring device idea when Dr. Konstantino left AST in 2002. A704 ¶ 3. Dr. Lotan put him in touch with a long-time cardiologist friend in the San Francisco Bay Area, Dr. Gary Gershony. A704, ¶ 5. Together, Drs. Gershony and Konstantino assembled a team and formed AngioScore in March 2003. A475-476, 16:12-17:6; A550; A704, ¶ 5.

Prior to AngioScore's formation, Dr. Konstantino had been collaborating with Mr. Feld, in Israel, to build initial prototypes of the scoring device in late 2002 and early 2003. A704, ¶¶ 4-6. Dr. Lotan evaluated the prototypes and gave feedback. A479-80, 20:24-21:6; A506-07, 55:22-56:4; A553 (referring to March 2003 meeting with Dr. Lotan to request "feedback on the design"). Dr. Konstantino filed a U.S. provisional patent application relating to the original spiral device on January 21, 2003. A374-89.

AngioScore subsequently filed a non-provisional application on July 30, 2003, that issued on March 30, 2010, as U.S. Patent 7,686,824 ("the '824 patent"). A556-76. AngioScore filed a continuation-in-part of this application on December 2, 2004, which issued on June 7, 2011, as U.S. Patent 7,955,350 ("the '350 patent"). A578-99. TriReme's suit for correction of inventorship centers around three patents that issued from continuation-in-part applications claiming priority from these original applications, but does not include the '824 and '350 patents.

B. Dr. Lotan's Inventive Contribution.

After Dr. Konstantino filed the provisional application in January 2003, he and Mr. Feld asked Dr. Lotan to perform an animal study to test prototypes of the scoring device. A704, ¶ 6. Dr. Lotan, and his colleague Dr. Meerkin, performed an animal study using what is known as a porcine coronary artery model at Hadassah's facilities in Jerusalem on April 14, 2003, with Dr. Konstantino and Mr. Feld in attendance. A414-18; A508-10, 57:13-59:2; A704-05, ¶¶ 6-8. Drs. Lotan and Meerkin summarized the study proceedings and recommendations in a report entitled "AngioScore Spiral Balloon Study 1." A518, 82:13-17; A414-18; A706, ¶ 11. The report bears the same date—April 14, 2003—that the study was conducted, and was transmitted two days later, on April 16, 2003. A691; A692.

Dr. Konstantino also summarized the results in an e-mail dated April 14, 2003. A601.

During the study, Dr. Lotan successively inserted five scoring devices or "spiral balloon" prototypes into the animal's arteries. Afterwards, he reported that "there is a clear retention problem," in which the spiral dislodged from the device upon retraction from the body in four out of five samples. A414-18. The problem arose because "the current bonding method is clearly inadequate and balloon retention of the spiral is a central issue." *Id*. at CL_000005. To address this problem, the report offers recommendations regarding bonding of the spiral and folding of the balloon. *Id*. at CL_000005.

Dr. Lotan later testified that the detachment described in his report took place inside the animal's body, where it was not visible, and that it was only after using his knowledge and experience to remove the device that the detachment could be seen. A542 at 139:14-24. He explained that skill was needed to retract the balloon and that "a combination of visualization and experience" was required to determine why the device failed. A522, 87:3-14. This was because "[i]t's not only the separation, but it's some of the concept behind it" that required evaluation. A521, 86:11-18. For this reason, "[y]ou do need to have experience, when something like this happens, to analyze what are the problems" because

experience and knowledge were required to "feel" the device as it was manipulated inside the body. A522-523, 87:16-88:9. Dr. Lotan had the necessary experience. A524-26, 89:10-91:2.

Dr. Lotan made additional contributions to the claimed inventions during two meetings he had with Dr. Konstantino and Mr. Feld after the study. The first meeting took place immediately after the procedure's conclusion. A508, 57:15-58:9; A601. Several days later, on April 21, 2003, the three met again to discuss the matter further. A707-10 (calendar entries showing animal study on April 14, 2003, and subsequent meeting with "Chaim Lotan" on April 21, 2003); A506-09, 55:10-58:9; A706, ¶ 11.

During these meetings, Dr. Lotan identified a critical problem with the then-existing scoring device prototypes, and recommended a solution—that both ends of the spiral should be bonded to the device in a way that would allow "on the one hand, good fixation but, on the other hand, have the structure move." A544-45, 141:24-142:16. The prototypes Dr. Lotan used for testing had spirals that were fixed at the distal end and "free-floating" at the proximal end. A603 (noting in March 2003, before the animal study, that "[p]roximal end is floating"); A704-05, ¶¶ 7-10. The proximal end had been left free floating, rather than

attached, because "it needs to have some motion in order to allow the balloon to expand and retract." A511, 60:14-25. Dr. Lotan, however, observed:

> [W]hen you deflate the balloon -- when one would -- deflates the balloon, those wires didn't come back together because it was free-floating. So when we were trying to retrieve the balloon to the catheter, there was a lot of pressures on the wire because they were not retracted, which caused disintegration of the distal part, bond, and the wire got separated from the balloon.

A511-12, 60:25-61:7.

To solve this problem, Dr. Lotan recommended the use of a polymer tube attached to the proximal end of the spiral at one end of the tube and the catheter at the other, rendering the spiral "semi-floating." A544-45, 141:24-142:16; A705-06, ¶¶ 10-11. This would have the benefit of allowing "both the axial and the rotational transmission as well as the retention of the wire." *Id*. A contemporaneous e-mail from Dr. Konstantino to Dr. Gershony and Mr. Tzori, among others, corroborates Dr. Lotan's account:

> We had a good experiment today with Chaim and David [Dr. Lotan's assistant]. We spent all day there until late evening discussing engineering aspects of the device. Chaim will send a full report probably within a day or two. . . . Four (4) out of five devices dislodged from the balloon due to poor bonding. []The proximal end was caught in the guide upon retrieval [a] few times. . . . ***We received a huge amount of design inputs that we didn't have until now. Next generations will be modified accordingly.*** Few immediate actions: -The distal bonding must be modified and tested before the 4/27 experiment (Nimrod) - The proximal end (floating) is already in design modification process using FEA modeling (Eitan,

Tanhum) - ***Proximal end should be protected by a polymer sleeve*** before 4/27 experiment (Nimrod).

A601 (emphases added).

Following the two meetings he had with Dr. Konstantino and Mr. Feld, Dr. Lotan had no further involvement in the design of the scoring device. A506-10, 55:10-59:2. Although he participated in some clinical trials of the finished product years later, he was not aware of any of AngioScore's development efforts after his involvement in April 2003. *Id.* It was not until years later, when he saw a commercial AngioSculpt device, that Dr. Lotan learned AngioScore had incorporated an attachment structure along the lines of his recommendations. A529-31, 95:20-97:24.

C. AngioScore Incorporated Dr. Lotan's Inventive Contribution Into the Patents-in-Suit.

AngioScore filed a continuation-in-part application to the '350 patent on August 13, 2004, which issued on December 20, 2011 as U.S. Patent 8,080,026 ("the '026 patent"). A606-33. AngioScore filed a continuation of that application on November 9, 2011, which issued on June 4, 2013 as U.S. Patent 8,454,636 ("the '636 patent"). A635-661. Finally, AngioScore filed a divisional of that application on March 15, 2013, which issued on May 13, 2014 as U.S. Patent 8,721,667 ("the '667 patent"). A663-89. Each of these three patents, which are

the Patents-in-Suit, lists the same three inventors from the two original AngioScore patents. None identify Dr. Lotan as an inventor.

Dr. Lotan testified that his inventive contribution is reflected in claim 1 of the '026 patent in at least the portion of the claim starting with "an attachment structure having a proximal end fixedly attached to the catheter body and a distal end attached to the proximal end of the external structure," through the end of the claim. A544-45, 141:14-142:23; A606-33. Claim 35 of the '026 patent, claim 1 of the '636 patent and claim 1 of the '667 include a corresponding limitation. A606-89. Figure 17a of each of the Patents-in-Suit illustrates this structure where a flexible elastomeric tube (258) attaches the spiral (252) to the catheter (256) via a bond between the spiral—also called the "external structure"—and the tube (264) and a bond between the tube and the catheter body (266):

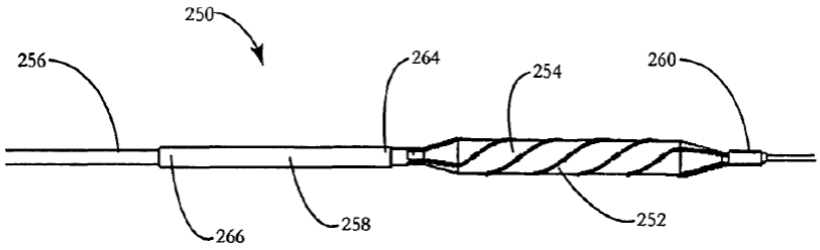


Fig. 17a

See, e.g., A630-31, 14:56-15:26.

D. Dr. Lotan Only Recently Discovered AngioScore's Failure to Name Him as an Inventor.

Dr. Lotan was not aware that AngioScore had incorporated his inventive contribution into any of the Patents-in-Suit until sometime in 2013. A490-91, 31:22-32:21. As the company grew and took on new management, Dr. Lotan's connection with its operation, including company financing and intellectual property, diminished. By 2014, Dr. Lotan learned, through a series of communications regarding his stock in the company, that his ownership interest had been diluted and questioned whether his inventive contribution had been included in AngioScore's patents without his knowledge. A481-485, 22:2-25:21; A486-88, 27:9-29:4; A471-73, 12:15-14:3. At that point, he considered seeking correction of inventorship. A490-91, 31:22-32:21.

Dr. Lotan approached Dr. Konstantino to see whether his recollection of Dr. Lotan's contribution matched. *Id.* Dr. Konstantino agreed that Dr. Lotan had made an inventive contribution, and offered to support his claim. A491-92, 32:22-33:11; A494-95, 35:14-36:1. Even with Dr. Konstantino's support, however, Dr. Lotan hesitated because "[i]t's not part of my nature to sue" and he "thought it would be too complex and expensive" for him—as a busy physician in Israel—to maintain a lawsuit in the U.S. A495, 36:1-12. After deciding not to

pursue a correction of inventorship claim on his own Dr. Lotan offered a license to TriReme. A494-95, 35:14-36:12.

E. Dr. Lotan's Agreements with AngioScore and TriReme.

Dr. Lotan and TriReme entered into an agreement on July 24, 2014. A317-32. In exchange for a lump sum, Dr. Lotan granted "to TriReme and its Affiliates a royalty-free, exclusive worldwide license" of "all legal and equitable rights held by Lotan, now or in the future" to the Patents-in-Suit or "any patents or patent applications claiming common priority" to them. A317-18. Dr. Lotan has confirmed that he retains no financial interest in the Patents-in-Suit and has no stake—monetary or non-monetary—in the present litigation. A497-98, 38:14-17, 39:6-9; A537, 107:21-23. The District Court's dismissal was in no way based on this agreement between TriReme and Dr. Lotan.

AngioScore and Dr. Lotan signed the May 2003 Agreement, entitled "AngioScore, Inc. Consulting Agreement," in October and November 2003, respectively. A309-15. The agreement sets its effective date as May 1, 2003. A309. Before either the effective date or the dates of execution of this agreement, AngioScore had received a copy of Dr. Lotan's report and recommendations from the April 14, 2003, animal study, as well as Dr. Konstantino's email summary of

Dr. Lotan's additional recommendations from the April 21, 2003 meeting. A691; A601.

At the outset, the May 2003 Agreement expressly limits its scope to services Dr. Lotan provided from May 1, 2003 through termination:

> 1. **Consulting Relationship.** *During the term of this Agreement,* Consultant will provide consulting services (the "Services") to the Company as described on Exhibit A.
>
> . . . .
>
> 4. **Term and Termination.** *This Agreement shall become effective on the Effective Date and remain in force until terminated* by either party . . . .

A309 (italics added). The agreement reinforces this temporal limitation with respect to Dr. Lotan's inventions.

Section 9 of the May 2003 Agreement, entitled "Inventions," has three subsections. The first, "(a) Inventions Retained and Licensed," confirms that Dr. Lotan retained his "Prior Inventions" and outlines the circumstances in which AngioScore would receive a nonexclusive license to them. The second, "(b) Assignment of Inventions," sets forth the conditions in which Dr. Lotan's "Inventions" arising during the term of the agreement would be assigned to AngioScore. The third, "(c) Further Assurances," is an undertaking by which Dr. Lotan agreed to help AngioScore secure intellectual property rights in the

"Inventions" subject to subsection 9(b). A310-11. Like Sections 1 and 4, these provisions make clear that Dr. Lotan's obligations to assign or license inventions were based on, and limited to, activities occurring on or after the May 1, 2003 effective date:

> 9. **Inventions.**
>
> (a) **Inventions Retained and Licensed.** Consultant has attached hereto, as part of Exhibit C, a list describing all inventions, original works of authorship, developments, improvements, and trade secrets which were made by Consultant prior to the date of this Agreement (collectively referred to as "Prior Inventions"), that belong solely to Consultant or belong to Consultant jointly with another and that relate to any of the Company's current or proposed businesses, products or research and development; or if no such list is attached, Consultant represents that there are no such Prior Inventions. If, ***in the course of providing the Services, Consultant incorporates*** into a Company product, process or machine or into any Invention (as defined below), a Prior Invention owned by Consultant or in which Consultant has an interest, the Company ***is hereby granted and shall have*** a non-exclusive, royalty-free, irrevocable, perpetual, worldwide ***license*** (with the right to sublicense) to make, have made, copy, modify, make derivative works of, use, sell and otherwise distribute such Prior Invention as part of or in connection with such product, process, machine or Invention.
>
> (b) **Assignment of Inventions.** Consultant agrees to promptly disclose to the Company and hereby assigns to the Company, or its designee, all right, title and interest in and to all inventions, original works of authorship, developments, concepts, know how, improvements or trade secrets, whether or not patentable, that ***Consultant may solely or jointly conceive or develop or reduce to practice during the term of this Agreement that relate to the Services*** (collectively referred to as "Inventions").

> (c) **Further Assurances.** Consultant shall execute all such documents and take all such actions as are requested by the Company to assist the Company, or its designee, at its expense, in every proper way to secure the Company, or its designee's, rights in the ***Inventions*** and any intellectual property rights relating thereto.

A310-11 (bold italics added).

Subsection 9(a) concerns "Prior Inventions" made before the effective date, which were to be listed in Exhibit C to the agreement. *Id.* Dr. Lotan did not list any inventions in Exhibit C and also did not check the blank for "No inventions or improvements." *Id*. At his deposition, Dr. Lotan testified that he did not list his April 2003 inventive contribution in Exhibit C because he did not consider it an invention at the time. A506-11, 55:10-59:2, 59:14-60:13; A515, 64:5-12.

Notwithstanding any language regarding Exhibit C, Subsection 9(a) has two conditions required to trigger a nonexclusive license of Dr. Lotan's "Prior Inventions." First, only Prior Inventions "which were made by Consultant" may qualify. A310. Dr. Lotan testified that he had no involvement beyond the April 2003 animal study and meetings. A506-10, at 55:10-59:2. Specifically, Dr. Lotan contributed the idea of adding an elastic tube to the prototype scoring catheter, but he was not involved in reducing to practice or "making" the scoring catheter before or after May 1, 2003. A506-11, 55:10-59:2; A529-31, 95:20-97:24; A544-45, 141:24-142:16; A705-06, ¶¶10-11. Second, Section 9(a) required Dr. Lotan to

grant a license only for Prior Inventions that Dr. Lotan ***himself*** incorporated into an AngioScore product "in the course of providing the Services." Again, Dr. Lotan testified that he had no involvement in the development of the AngioSculpt product after April 2003, and was not involved in making the device. *Id*. He did not discover that AngioScore had incorporated his inventive contributions into its product, and the Patents-in-Suit, until years later. A490-91, 31:22-32:21; A529-31, 95:20-97:24. Thus it was others, and not Dr. Lotan, that incorporated his inventive contribution into an AngioScore product.

SUMMARY OF THE ARGUMENT

The district court erred in finding that the May 2003 Agreement operated to assign Dr. Lotan's rights to AngioScore, thereby leaving Dr. Lotan unable to assign his rights—and convey standing—to TriReme.

Pursuant to the plain language of Paragraph 9(a) of the May 2003 Agreement, AngioScore would get a license to Dr. Lotan's "Prior Inventions" if—and only if—Dr. Lotan incorporated them into an AngioScore product or Invention while providing services during the term of the agreement. He did not do so. Thus, AngioScore was not granted a license under Paragraph 9(a). There is no language in Paragraph 9(a) regarding assignment. Nor does Paragraph 9(a) state that rights to any inventions not listed were not preserved. The district court,

however, erroneously strayed from the plain language of the provision, professed to divine the parties "intention," and construed the word "Retained" in the header of Paragraph 9(a) to mean that Dr. Lotan forfeited his rights to any inventions not listed as "Prior Inventions." The district court's interpretation of Paragraph 9(a) is contrary to fundamental principles of contract interpretation.

The only assignment clause in the May 2003 Agreement is in Paragraph 9(b), and that paragraph only operates to assign inventions that the Consultant "solely or jointly conceive[d] or develop[ed] or reduce[d] to practice during the term of this Agreement that relate to the Services." Dr. Lotan's inventive contributed to the conception of the modified scoring device in April 2003, and did not thereafter contribute to the conception, development or reduction to practice of the device or the inventions claimed in the Patents-in-Suit. Thus, Dr. Lotan did nothing on or after May 1, 2003, to trigger the assignment provisions of Paragraph 9(b). Even if the district court correctly held that Dr. Lotan failed to preserve his rights under Section 9(a), the rights to his inventive contribution still would not be assigned under Paragraph 9(b) because his contribution was not made during the term of the agreement, which began on May 1, 2003. Accordingly, Dr. Lotan's rights were never assigned to AngioScore. Rather, Dr.

Lotan exclusively licensed TriReme to his rights in the Patents-in-Suit in 2014, thereby conveying to TriReme standing to pursue Dr. Lotan's claims.

STANDARD OF REVIEW

Standing to sue is a question of law this Court decides *de novo*. *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1355 (Fed. Cir. 2001) (citing *Prima Tek II LLC v. A-Roo Co.*, 222 F.3d 1372, 1376 (Fed. Cir. 2000)).

The grant of a motion to dismiss is reviewed *de novo*. *Chou*, 254 F.3d at 1355. "Dismissal is proper only if, after drawing all reasonable inferences in [appellant's] favor, it is clear that the appellant can prove no set of facts consistent with [appellant's] claim that would entitle [appellant] to relief." *Id.*

Interpretation of a contract is a question of law, which this Court reviews *de novo*. *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1569 (Fed. Cir. 1993).

ARGUMENT

I. DR. LOTAN'S INVENTIVE CONTRIBUTION WAS NOT COVERED BY PARAGRAPH 9(a) OF THE MAY 2003 AGREEMENT.

The district court based its erroneous ruling in part on Paragraph 9(a) of the May 2003 Agreement, which it mischaracterizes as a "carve-out" provision. A10. Per the court, because Dr. Lotan did not "retain" his rights in the invention under Paragraph 9(a), "he did not save those rights from being assigned to AngioScore."

Id. The district court's interpretation runs afoul of the plain language of Paragraph 9(a), which is nothing more than a license provision and was never invoked here.

A. The Plain Language of Paragraph 9(a) Dictates that it is a License Provision Only.

The two sentences of Paragraph 9(a) are straightforward. The first simply states that Consultant has provided a list of Prior Inventions, as defined therein, and if no list has been provided, Consultant represents that there are no such Prior Inventions:

> Consultant has attached hereto, as part of Exhibit C, a list describing all inventions, original works of authorship, developments, improvements, and trade secrets which were made by Consultant prior to the date of this Agreement (collectively referred to as "Prior Inventions"), that belong solely to Consultant or belong to Consultant jointly with another and that relate to any of the Company's current or proposed businesses, products or research and development; or, if no such list is attached, Consultant represents that there are no such Prior Inventions.

A310, ¶ 9(a).[1]

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[1] The parties do not dispute that the bottom portion of Exhibit C was left blank. Not only is nothing listed in the bottom portion of Exhibit C, but the space for "No inventions or improvements" was left unchecked. A315. Dr. Lotan explained that he did not believe that the modification to the prototype scoring device that he proposed in April 2003—the addition of the elastic tube attachment structure—constituted a standalone invention. A349-50. Moreover, no patent or patent application incorporating Dr. Lotan's contribution had been prepared as of (continued . . .)

Pursuant to the second sentence, if *Consultant* incorporates a Prior Invention into an AngioScore product or Invention in the course of providing the Services, AngioScore is granted a non-exclusive license to the Prior Invention:

> If, in the course of providing the Services, Consultant incorporates into a Company product, process or machine or into any Invention (as defined below), a Prior Invention owned by Consultant or in which Consultant has an interest, the Company is hereby granted and shall have a non-exclusive royalty-free, irrevocable, perpetual, worldwide license (with the right to sublicense) to make, have made, copy, modify, make derivative works of, use, sell and otherwise distribute such Prior Inventions as part of or in connection with such product, process, machine or Invention.

A310, ¶ 9(a).

Accordingly, Paragraph 9(a) simply operates to grant AngioScore a license to Prior Inventions that Dr. Lotan, in the course of providing Services, incorporated into AngioScore's products or Inventions. By its terms, it does not do anything else. It does not purport to assign any rights to AngioScore, nor does it state that Consultant somehow ***loses*** any rights to inventions that are not listed. Indeed, under the *expressio unius est exclusio alterius* doctrine, expression of one thing (a license) results in the exclusion of another (an assignment). *See, e.g.*, *Stephenson v. Drever*, 16 Cal. 4th 1167, 1175 (1997) ("The fact that the contract

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(. . . continued)
November 2003, when Dr. Lotan signed the May 2003 Agreement. *Compare* A312 *with* A57 (reflecting August 13, 2004, filing date).

expressly so provides tends to negate any inference that the parties also intended another consequence to flow from the same event.").

The district court focused on the absence of any information on the bottom half of Exhibit C, and the representation in Paragraph 9(a) that "if no such list is attached, Consultant represents that there are no such Prior Inventions." *See* A10 (agreement stated "in plain language, that if no such material was listed, then Dr. Lotan represented that there was no such work."). The district court, however, largely ignored the second sentence, supplanting it with a "carve-out clause" cobbled together from Paragraph 9(a)'s heading and the "manifest intent" of the parties.

By its plain terms, the second sentence of Paragraph 9(a) could result, at most, in a non-exclusive license to AngioScore. That did not happen here because Dr. Lotan did not incorporate any Prior Invention into an AngioScore product, process, machine or Invention "[i]n the course of providing the Services." A349, A352. Whether Dr. Lotan listed Prior Inventions in Exhibit C makes no difference in this context. But even if the license provision were somehow invoked, the grant of a non-exclusive license would not deprive TriReme of standing. AngioScore did not argue to the contrary, and the district court did not reach a contrary conclusion.

B. The use of "Retained" in the Heading of Paragraph 9(a) Does Not Change the Plain Meaning of the Paragraph's Terms.

The district court characterized Paragraph 9(a) as a "'carve-out,' under which Dr. Lotan could identify and retain (*i.e.* not assign to AngioScore) his rights in any preexisting work." A8. The district court rests its interpretation not on the two sentences that make up the paragraph, but rather on the use of the word "Retained" in the heading. A10. The presence of the word "Retained" in the heading does not impact the operative language of the paragraph, which deals with listing "Prior Inventions" and, under certain specific circumstances, licensing them to AngioScore. Importantly, the heading "Retained" does not conjure a *new* sentence dictating that any inventions not listed are therefore not "Retained" by Dr. Lotan but subject to assignment to AngioScore. The parties could have added language to that effect, but they did not. The Court should not do so either. Far from "mangling the express terms of the consulting agreement" (*id.*), *TriReme's* interpretation adheres to the actual terms of the May 2003 Agreement. TriReme does not propose to add new terms where none exist.

The only reasonable interpretation of "Retained" is that Dr. Lotan retained his prior inventions whether listed or unlisted. That interpretation is consistent with the language of Paragraph 9(a) itself, which nowhere states that the consequence of failing to list a Prior Invention is assignment. Furthermore, the

word "retained" necessarily refers to maintaining the status quo with respect to the Consultant's rights, not Angioscore's. Only the Consultant, as the party owning Prior Inventions at the time of signing, could "retain," rather than receive, them. *See Bd. of Trs. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188, 2195 (2011) ("Our precedents confirm the general rule that rights in an invention belong to the inventor."); *see also id.* at 2192 ("Since 1790, the patent law has operated on the premise that rights in an invention belong to the inventor."). Otherwise, the heading would not be "Inventions Retained and Licensed," but rather "Inventions Assigned," "Inventions Conveyed," or "Inventions Forfeited."

C. The District Court Erroneously Used the Presumed "intention" of the Parties to Contradict the May 2003 Agreement's Unambiguous, Express Terms.

Despite advocating adherence to the "plain" and "express language of the consulting agreement" (A9-10), the district court disregarded the actual language used by the parties by improperly adding a "carve-out" provision to fulfill what it believed to be the May 2003 Agreement's "objectively apparent intent." A12-14. Although maintaining that the "purpose is apparent from the contract's plain language," the district court's entire analysis is premised on "the context that spawned the contract" and the "objectively apparent intent of the whole

agreement," *i.e.*, something other than the Agreement's actual terms.[2] A13-14. Resort to such extrinsic evidence[3] is unwarranted given the plain and unambiguous terms of the Agreement.

TriReme's interpretation of the Agreement is wholly consistent with well-settled principles of California[4] contract law. As the district court noted, "California recognizes the objective theory of contracts, under which it is the *objective intent, as evidenced by the words of the contract*, rather than the subjective intent of one of the parties, that controls interpretation." A12-13 (quoting *Cedars–Sinai Med. Ctr. v. Shewry*, 137 Cal. App. 4th 964, 980 (2006)). "When a contract is reduced to writing, the intention of the parties is to be ascertained *from the writing alone*, if possible . . . ." Cal. Civ. Code § 1639 (emphasis added). Furthermore, "[t]he language of a contract is to govern its

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[2] In fact, the district court appends a footnote to its proclamation that the "purpose is apparent from the contract's plain language" advocating the appropriateness of "consider[ing] the surrounding circumstances" and looking to "extrinsic evidence" in interpreting contracts. A14 & n.4.

[3] Despite purporting to analyze extrinsic evidence relating to the circumstances surrounding the Agreement, the district court's discussion does not cite to ***any*** evidence. A13-14. This is unsurprising because AngioScore did not present any extrinsic evidence concerning AngioScore's interpretation of Paragraph 9(a), and Dr. Lotan testified that he did not believe his inventive contribution to the prototype scoring device constituted a Prior Invention that he had to list. A349-50.

[4] Pursuant to Paragraph 12(c) of the Agreement, California law governs the interpretation, construction and performance of the Agreement. A311, ¶ 12(c).

interpretation, if the language is clear and explicit, and does not involve an absurdity." Cal. Civ. Code § 1638. "The whole of a contract is to be taken together, so as to give effect to every part, if reasonably practicable, each clause helping to interpret the other." *Navarro v. Mukasey*, 518 F.3d 729, 734 (9th Cir. 2008) (applying California law). Only "[w]ords in a contract which are wholly inconsistent with its nature, or with the main intention of the parties, are to be rejected." Cal. Civ. Code § 1653.[5]

The court's "function is to determine what, in terms and substance, is contained in the contract, not to insert what has been omitted. [The court does] not have the power to create for the parties a contract that they did not make and cannot insert language that one party now wishes were there." *Dameron Hosp. Ass'n v. AAA N. Cal., Nev. & Utah Ins. Exch.*, 229 Cal. App. 4th 549, 569 (2014) (quoting *Vons Cos., Inc. v. United States Fire Ins. Co.*, 78 Cal. App. 4th 52, 58-59 (2000)). "[C]ourts cannot make better agreements for parties than they

[5] The district court professed to give Cal. Civ. Code § 1653 a "short extension" to "reject proposed *interpretations* that are wholly inconsistent with a contract's nature, or with the parties' (objectively apparent) main intention." A12 (internal quotation marks omitted). The district court's application of § 1653 to the parties' presumed "intention" was erroneous. *See, e.g., Supervalu, Inc. v. Wexford Underwriting Managers, Inc.*, 175 Cal. App. 4th 64, 75-76 (2009), *as modified* (June 24, 2009) (refusing to give special meaning to contract term where policy language was clear, explicit and did not involve an absurdity because "the parties agreed to the policy language and [the court had] no power to rewrite it.").

themselves have been satisfied to enter into or rewrite contracts because they operate harshly or inequitably. It is not enough to say that without the proposed implied covenant, the contract would be improvident or unwise or would operate unjustly. Parties have the right to make such agreements. The law refuses to read into contracts anything by way of implication except upon grounds of obvious necessity." *Id.* at 569-70 (quoting *Frankel v. Bd. of Dental Exam'rs*, 46 Cal. App. 4th 534, 545 (1996)) (alterations original). Accordingly, it was improper for the district court to go beyond the actual terms of the Agreement and create a new provision depriving Dr. Lotan of any rights to unlisted Prior Inventions.

As detailed above, by its express terms, Paragraph 9(a) is a license provision—not a carve-out. Although the district court believed TriReme to be "hyper-pars[ing]" the contract and "[n]aming each letter," but "fail[ing] to read the word," (A12-13), there is nothing in the May 2003 Agreement, taken as a whole, that is inconsistent with TriReme's interpretation or leads to a different conclusion. The May 2003 Agreement is a typical consulting agreement governing the relationship between AngioScore and Dr. Lotan. It covers the term and scope of the services Dr. Lotan agreed to provide and the compensation he would receive in return. *See* A309-10. Paragraph 9 is the only paragraph dealing with "Inventions" (recognized by the district court as containing "the consulting

agreement's two salient clauses (paragraphs 9(a) and 9(b))) (A13)) and, as such, is the focus of the analysis. TriReme's interpretation adheres to the language of Paragraph 9 and does not contradict any other provisions of the May 2003 Agreement.

Indeed, one of the errors that led the *district court* astray was taking the word "Retained" in isolation and giving it a significance unwarranted by the operative language of Paragraph 9 and the May 2003 Agreement as a whole. Viewing the word "Retained" in isolation as meaning that AngioScore "Retained" any of Dr. Lotan's unlisted Prior Inventions, the district court rewrote the May 2003 Agreement to add a *new* provision depriving Dr. Lotan of his rights.

Another error in the district court's interpretation of the agreement was its use of Exhibit C to rewrite Paragraph 9(a). The representation contained in Paragraph 9(a)—that "if no such list [Exhibit C] is attached, Consultant represents that there are no such Prior Inventions"—neither expresses any forfeiture nor evidences an intent by the parties to create one. The "representation" in Paragraph 9(a) is also inconsistent with Exhibit C, which includes the words "No inventions or improvements," next to a space that Dr. Lotan ***did not check***. No evidence reflects that AngioScore ever raised or questioned this inconsistency at the time.

Regardless, even if Dr. Lotan should have represented that he had "Prior Inventions" on Exhibit C (and TriReme disagrees that any such representation should have been made), the consequence of failing to list a "Prior Invention" is not automatic assignment. Likewise, even if Dr. Lotan had made an erroneous representation that he had no Prior Inventions, such a representation would not change the reality of his inventive contribution, which is supported by substantial evidence. Such an error also would not convert the May 2003 Agreement's license provision into an implied assignment provision. Nothing in Paragraphs 9(a) or 9(b) leads to that result. As discussed above, Paragraph 9(a) provides only for a non-exclusive license to AngioScore of a Prior Invention under specific circumstances, whereas Paragraph 9(b) recites specific assignment provisions relating to Inventions arising during the agreement's terms, as discuss below.

Finally, to the extent there is any ambiguity in the meaning of Paragraph 9(a), it should be resolved against AngioScore. "It is a well-settled rule of law that ambiguities in a written contract are to be construed against the party who drafted it." *Victoria v. Superior Court*, 40 Cal. 3d 734, 745 (1985) (citing cases); Cal. Civ. Code § 1654 ("In cases of uncertainty . . . the language of a contract should be interpreted most strongly against the party who caused the uncertainty to exist."). Here, AngioScore drafted the Agreement. A33, A724 n.4. If there is

any ambiguity as to the effect of the word "Retained" in Paragraph 9(a), it should be resolved against AngioScore and should not operate to deprive Dr. Lotan of his rights to unlisted inventions.

II. DR. LOTAN'S INVENTIVE CONTRIBUTION WAS NOT COVERED BY THE ONLY ASSIGNMENT CLAUSE OF THE MAY 2003 AGREEMENT—PARAGRAPH 9(b).

The lone assignment clause in the May 2003 Agreement is Paragraph 9(b) which, by its terms, applies only to inventions that Dr. Lotan "solely or jointly conceive[d] or develop[ed] or reduce[ed] to practice during the term of this Agreement that relate to the Services." A310 at ¶ 9(b). As the Effective Date of the agreement is May 1, 2003, and the evidence establishes that (1) Dr. Lotan contributed to conception in April, 2003, and (2) thereafter did not solely or jointly conceive, develop or reduce to practice the inventions claimed in the Patents-in-Suit, the assignment clause could not operate to assign Dr. Lotan's rights to AngioScore.

A. Dr. Lotan did Not Make His Inventive Contribution During the Term of the May 2003 Agreement.

The evidence of record establishes that Dr. Lotan had completed his contribution to the inventions later claimed in the Patents-in-Suit by April 21, 2003, when he had a follow-up meeting with Dr. Konstantino and Mr. Feld. Indeed, Dr. Lotan testified that he played no role in developing the scoring device

after that second meeting, and he did not know his contribution had been incorporated into AngioScore's scoring device until years later. A342, A348-349, A358-59. Dr. Lotan's report on the April 14, 2003, animal study, and Dr. Konstantino's April 21, 2003, email memorialize Dr. Lotan's April 2003 contribution to conception.

Dr. Lotan's continued work "on catheter-related issues under the terms of his consulting contract with AngioScore" in May 2003 and beyond (A14) does not provide the missing basis for an assignment because such work does not amount to "conceive[ing] or develop[ing] or reduce[ing the invention] to practice during the term of [the] Agreement." A310 at ¶ 9(b). Merely "talking" with AngioScore and "plann[ing] on human studies," (some of which came to pass, and some of which did not), conducting studies, and helping to interpret the clinical data (*see* A348, A353, A366) does not rise to the level of conceiving, developing, or reducing the invention to practice.

Rather, Dr. Lotan's post-May 1, 2003, work was directed at shepherding the invention through the various obstacles that must be surmounted to obtain regulatory approval. As Dr. Lotan explained, his work during the term of the May 2003 Agreement was not directed to the catheter itself, but rather "to the clinical outcomes in patients" on whom the catheter was used. A366, 126:5-127:5. As it

turned out, the catheter worked "[q]uite nicely" and Dr. Lotan did not recall any problems. *Id*. Indeed, the district court correctly acknowledged "that Dr. Lotan's work during the consulting agreement [may have] amounted to collecting regulatory data on a finished device," and "assum[ed] that the inventive contribution was complete by April 2003."[6] A15. Accordingly, Dr. Lotan could not have assigned his rights in inventions claimed in the Patents-in-Suit because he did not solely or jointly conceive, develop, or reduced to practice on or after May 1, 2003, *i.e.*, during the term of the May 2003 Agreement.

Furthermore, to the extent the resolution of the jurisdictional issue comes down to an issue of fact—whether Dr. Lotan's post-April 2003 work amounted to "conceive[ing] or develop[ing] or reduce[ing] to practice during the term of this Agreement" (A310), even though AngioScore presented ***no evidence*** to the contrary—the presence of such a factual dispute plainly warrants reversal of the district court's decision. The Ninth Circuit has held: "Jurisdictional finding of genuinely disputed facts is inappropriate when the jurisdictional issue and substantive issues are so intertwined that the question of jurisdiction is dependent on the resolution of factual issues going to the merits of an action." *Sun Valley*

[6] As discussed below, the district court erroneously held that the timing of the inventive contribution did not matter. A15.

Gasoline, Inc. v. Ernst Enters., Inc., 711 F.2d 138, 139 (9th Cir. 1983) (citations and internal quotation marks omitted).

This dispute of fact is central to AngioScore's standing argument because it is determinative of whether any of Dr. Lotan's rights were conveyed to AngioScore pursuant to the May 2003 Agreement and, at that same time, goes to the nature and timing of Dr. Lotan's inventive contribution—facts at the heart of TriReme's claim for correction of inventorship. What Dr. Lotan did and when he did it go both to jurisdiction and the merits of the case, thus requiring denial of AngioScore's Motion by the district court and reversal of the district court's order here. *See Swanson v. Alza Corp.*, No. C 12-4579 PJH, 2013 WL 968275, at *5 (N.D. Cal. Mar. 12, 2013) (denying motion to dismiss correction of inventorship case due to "numerous factual disputes" relating to both inventive contribution and question of standing arising out of consulting agreement).

B. The Assignment Clause Does Not Cover Dr. Lotan's Pre-May 1, 2003, Contribution to Conception of the Inventions Claimed in the Patents-in-Suit.

In light of its erroneous interpretation of Paragraph 9(a), the district court held that the lack of an inventive contribution during the term of the Agreement would not change the outcome because any interest Dr. Lotan had was swept into the Agreement and assigned to AngioScore. A15. The district court's

interpretation runs afoul of the plain language of Paragraph 9(b) (as well as Paragraph 9(a)).

Even if Dr. Lotan should have listed his April 2003 suggestion to modify the prototype scoring device as a Prior Invention on Exhibit C, Paragraph 9(a) *still* would not operate to assign Dr. Lotan's rights to AngioScore. By its terms Paragraph 9(b) assigns only inventions arising "during the term of [the] Agreement that relate to the Services."[7] A310 ¶ 9(b). In light of these unambiguous limitations on the assignment clause, the absence of any language concerning Dr. Lotan's April 2003 contribution on Exhibit C is irrelevant. As Dr. Lotan contributed to conception of a modified scoring device in April 2003 and the effective date of the May 2003 Agreement was May 1, 2003, Dr. Lotan's inventive contribution was not made "during the term of [the] Agreement."[8] A310 at ¶ 9(b). Consequently, Dr. Lotan's rights were not assigned to AngioScore.

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[7] The reference to "Services" in Paragraph 9(b) reinforces the temporal limitation on the assignment clause. "Services" are defined in Paragraph 1 as the consulting services that the Consultant will provide "[d]uring the term of this Agreement." A309.

[8] AngioScore knew of Dr. Lotan's work in April 2003 because AngioScore received a copy of the April 14, 2003, animal study no later than April 24, 2003. A691-96.

III. THE DISTRICT COURT'S "ANALOGIES" ARE NOT ANALOGOUS.

In a section entitled "Analogies," the district court discussed several cases purportedly consistent with its finding that Dr. Lotan's interest was assigned to AngioScore, thereby depriving TriReme of standing because Dr. Lotan had nothing left to assign. A15-16. Those cases are readily distinguishable.

According to the district court, the situation here was "effectively identical" to *Larson v. Correct Craft, Inc*., 569 F.3d 1319, 1325-27 (Fed. Cir. 2009). A15. In *Larson,* the Federal Circuit held that the plaintiff lacked standing where it was undisputed that he had assigned title in the relevant patents to the defendant under an employment contract. *Larson*, 569 F.3d at 1322, 1326-27. Here, however, assignment is anything but a foregone conclusion. Indeed, it is the very issue at the heart of the jurisdictional controversy. And unlike Larson, Dr. Lotan did *not* assign his interest to AngioScore for the reasons detailed at length above. Accordingly, absent such an assignment, he was able to—and did—convey an exclusive license to TriReme in 2014.

In reaching its decision, the *Larson* court drew on its decision in *Jim Arnold Corp. v. Hydrotech Systems, Inc*., 109 F.3d 1567, 1571-75 (Fed. Cir. 1997), which is also distinguishable. There too, the plaintiff had already "assigned away all his . . . rights" and thus had "no ownership interest" in the subject patents. *Larson*,

569 F.3d at 1327 (discussing *Jim Arnold*, 109 F.3d at 1571-72). Consequently, the plaintiff in *Jim Arnold* lacked standing to pursue his claim in federal court. 109 F.3d at 1572. Again, because Dr. Lotan did not assign his rights to AngioScore, he was able to later to convey an exclusive license to TriReme, which is a sufficient interest for TriReme to have standing under 35 U.S.C. § 256.

Finally, the district court looked to *IMATEC, Ltd. v. Apple Computer, Inc*., 15 F. App'x 887 (Fed. Cir. 2001), and *Preston v. Marathon Oil Co*., 684 F.3d 1276, 1285 (Fed. Cir. 2012). A15-16. Both *IMATEC* and *Preston* were cases brought by a former employee whose inventive activities were governed by invention assignment provisions in their employment contracts, and both are inapposite, as they involve facts significantly different from the situation here.

In *IMATEC,* the inventor entered into an "Agreement with Respect to Assignment of Inventions and Confidential Information" on April 29, 1987, ***prior to*** beginning work on June 29, 1987. *IMATEC, Ltd. v. Apple Computer, Inc*., 81 F. Supp. 2d 471, 477-78 (S.D.N.Y. 2000). The Agreement's assignment clause read as follows:

> I agree to assign, and hereby do assign, to FONAR … all my rights to inventions which I have made or conceived or which I may hereafter make or conceive, either solely or jointly with others, in the course of [my] employment [by FONAR], or with the use of the time, material or facilities of FONAR, or relating to any product, method,

> substance, machine, article of [ ] manufacture or improvements therein with the scope of the business of said FONAR….

Id. at 478. "The plaintiffs admitt[ed] that the invention claimed in [the patents at issue] were reduced to practice in November 1987, while [the inventor] Dr. Shalit was employed by FONAR." *Id*. Thus, the assignment provision of the agreement unquestionably covered an invention that Dr. Shalit "made," *i.e.*, reduced to practice, in the course of employment in November 1987 *after* the execution of the Agreement in April 1987 and commencement of employment in June 1987. This is the opposite of the instant case. Dr. Lotan contributed to the conception of a modified scoring device in April 2003. He, however, signed the May 2003 Agreement in November 2003 and the May 2003 Agreement by its terms does not provide for assignment prior to its May 1, 2003, effective date.

Although not reproduced verbatim in the opinion and order, the agreement in *IMATEC* contained language that "[b]y its terms . . . excludes patents issued prior to Dr. Shalit's employment by FONAR and such inventions . . . listed in a blank space provided for the purpose." 81 F. Supp. 2d at 478. In that blank space, Dr. Shalit had written "photographic video recording for keeping records of video tape content." *See id.* & n.2. Dr. Shalit and IMATEC argued that the handwritten note excluding "photographic video recording for keeping records of video tape content" covered the claimed inventions. *See id.* at 482. The court disagreed,

finding that it did "not describe the inventions covered by the patents-in-suit. On its face, the exclusion applies to keeping records of video tape content." *Id.* The patents-in-suit, on the other hand, covered "a method and system for the accurate reproduction of the tone and luminance of a monitor display." *Id.* As the assignment "exclusion" language is not reproduced in the *IMATEC* opinion and it was undisputed that Dr. Shalit conceived and reduced to practice the claimed inventions while employed at FONAR, *IMATEC* did not address the situation where the assignment clause, on its face, does extend to activities prior to the term of the agreement.

In affirming the district court's judgment, this Court noted the breadth of the assignment provision in Dr. Shalit's agreement with FONAR. "So long as he had not excluded his invention from the scope of the contract, Dr. Shalit ***expressly*** granted to FONAR his rights in any invention ***he had already created*** and in any invention he developed while an employee of FONAR." 15 Fed. App'x at 893 (emphasis added). The Court undoubtedly came to this conclusion because the assignment provision provided for assignment of all inventions "made or conceived or which I may hereafter make or conceive . . . [1] in the course of [my] employment [by FONAR], ***or*** [2] with the use of the time, material or facilities of FONAR, ***or*** [3] relating to any product, method, substance, machine, article of [ ]

manufacture or improvements therein with the scope of the business of said FONAR…." 81 F. Supp. 2d 471 at 478. Thus, Dr. Shalit had expressly agreed to assign prior inventions if they related to the scope of FONAR's business. Not all assignment provisions are created equal. As noted above, the assignment provision in the May 2003 Agreement is much narrower because it is limited to certain inventive activity occurring only during the term of the Agreement.

The question in *Preston* was whether Preston owned two patents or had assigned rights in those patents to Marathon. 684 F.3d at 1278. Preston signed an employment letter on February 27, 2001, started working for Marathon on March 30, 2001, and signed a second employee agreement on April 5, 2001 (the "April Employee Agreement"). *Id.* at 1278-79 & n.1. The April Employee Agreement had a provision by which Preston assigned to Marathon "all Intellectual Property," with "Intellectual Property" being defined as "all inventions . . . ***made or conceived*** by [Preston] during the term of employment with MARATHON which (1) relate to the present or reasonably anticipated business of the MARATHON GROUP, or (2) were made or created with the use of Confidential Information or any equipment, supplies, or facilities of the MARATHON GROUP." *Id.* at 1279 (emphasis added).

The April Employee Agreement further contained a provision requiring Preston to provide a "list and brief description of all of EMPLOYEE'S unpatented inventions," which Marathon expressly agreed were not "Intellectual Property" and not the property of Marathon. *Id.* The provision continued: "If no listing is made, [Preston] has no such inventions or properties." *Id.* Under that provision—Paragraph 4—Preston wrote: "CH4 Resonating Manifold." *Id.*

Although Preston contended that he came up with the idea for the two patents prior to being employed by Marathon, "there [was] no dispute . . . that he never 'made' the invention (*i.e.*, physically constructed it) before joining Marathon." *Id.* at 1282. "The plain language of paragraph 1(d) of the agreement indicates that any 'invention' that is 'made ***or*** conceived' by an employee while employed at Marathon constitutes 'Intellectual Property' and is therefore automatically assigned to Marathon under Paragraph 3. . . . Thus, if Preston's invention was not both made ***and*** conceived prior to his employment, it constitutes 'Intellectual Property' under Paragraph 1 of the April Employee Agreement." *Id.* at 1286. Based on the plain language of the April Employee Agreement, conception prior to employment was irrelevant because Preston had made the invention during the term of employment.

As a separate argument that he had not assigned the patent inventions to Marathon, Preston argued that he had excluded them by listing "CH4 Resonating Manifold" under Paragraph 4 of the April Employee Agreement. *Id.* at 1286. But, the district court concluded, and this Court agreed, that, whatever was meant by the words "CH4 Resonating Manifold," Preston had not demonstrated invention of the technology claimed in the two patents at issue prior to employment at Marathon. *Id.* at 1287-88. Accordingly, the language of Paragraph 4 did not apply to exclude the two patents from the April Employee Agreement's assignment provision. *Id.* at 1288.

The instant case, unlike *Imatec* or *Preston*, does not turn on resolution of the meaning or effect of an identification of previously invented subject matter such as "photographic video recording for keeping records of video tape content" or "CH4 Resonating Manifold." Here, unlike in *Imatec* or *Preston,* Dr. Lotan made his contribution before the term of the May 2003 Agreement, and thereafter did not contribute to the conception, development or reduction to practice of the modified scoring device. Therefore, Dr. Lotan's contribution does not come within the scope of the assignment clause. This is not a tortured reading of Paragraph 9(b); the assignment clause, by its terms, only covers Dr. Lotan's inventive activities "during the term." A310. Unlike in *Preston,* it ***does matter***

that Dr. Lotan contributed to conception before May 1, 2003, because Dr. Lotan did not make (or conceive or develop or reduce to practice) on or after May 1, 2003. Since Dr. Lotan's April 2003 contribution is ***not captured*** by the language of the assignment clause, it is irrelevant whether Paragraph 9(a) ***excludes*** it.

Thus, the May 2004 Agreement resulted in no assignment of Dr. Lotan's inventive contribution to the Patents-in-Suit to AngioScore and TriReme has standing to sue for correction of inventorship as Dr. Lotan's exclusive licensee.

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CONCLUSION

Accordingly, for the foregoing reasons, the Court should reverse the district court's Order granting AngioScore's Motion to Dismiss and should remand the case for further proceedings.

DATED: May 29, 2015

Respectfully,

By */s/ David A. Caine*
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ADDENDUM

ADDENDUM TABLE OF CONTENTS

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

San Francisco Division

TRIREME MEDICAL, LLC,

Plaintiff,

v.

ANGIOSCORE, INC.,

Defendant.

Case No. 14-cv-02946-LB

JUDGMENT

On March 17, 2015, the Court granted defendant AngioScore, Inc.'s motion to dismiss the plaintiff's complaint. (ECF No. 41.) Pursuant to Federal Rule of Civil Procedure 58, the Court hereby ENTERS judgment in favor of AngioScore and against plaintiff TriReme Medical, LLC. The Clerk of Court shall close the file in this matter.

IT IS SO ORDERED.

Dated: March 31, 2015

LAUREL BEELER
United States Magistrate Judge

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

San Francisco Division

TRIREME MEDICAL, LLC,

Plaintiff,

v.

ANGIOSCORE, INC.,

Defendant.

Case No. 14-cv-02946-LB

ORDER GRANTING MOTION TO DISMISS

[Re: ECF No. 36]

INTRODUCTION

This is a case for correction of patent inventorship under 35 U.S.C. § 256. (ECF No. 1 at 2, ¶ 3.)[1] Plaintiff TriReme Medical, LLC's claims involve the alleged inventive contributions that a third party, Dr. Chaim Lotan, made to an angioplasty balloon catheter that defendant AngioScore, Inc. manufactures. AngioScore contends that Dr. Lotan assigned whatever rights he had in the device to AngioScore in 2003; TriReme argues that Dr. Lotan licensed his rights in the device to TriReme in 2014. The court concludes that Dr. Lotan assigned whatever rights he had to AngioScore under a 2003 consulting agreement. He thus had nothing to license to TriReme in 2014. TriReme has no interest in the subject patents sufficient to maintain a § 256 claim, and it

[1] Record citations are to material in the Electronic Case File ("ECF"); pinpoint citations are to the ECF-generated page numbers at the tops of documents.

thus lacks standing. The court accordingly dismisses TriReme's case. *See, e.g., Larson v. Correct Craft, Inc.*, 568 F.3d 1319 (Fed. Cir. 2009); *Jim Arnold Corp. v. Hydrotech Sys., Inc.*, 109 F.3d 1567 (Fed. Cir. 1997).[2]

STATEMENT

This case concerns three patents issued on a medical device: a balloon catheter used in angioplasty to remedy obstructions (such as plaques) in the peripheral vascular system. (The relevant patents are: No. 8,080,026; No. 8,454,636; and No. 8,721,667 — all being U.S. patents. (ECF No. 1 at 2, ¶ 7; *see* ECF No. 37 at 10, 13.))[3] AngioScore owns these patents by assignment and manufactures the angioplasty balloon catheter to which they relate. The device's inventors include Dr. Eitan Konstantino (who founded AngioScore and later left to found TriReme) and Tanhum Feld. Dr. Chaim Lotan — who is not a party to this suit; and who is not listed as an inventor on the patents — is an Israeli cardiologist who claims to have contributed to early work on the catheter and so to have inventors' rights in the subject patents. Dr. Lotan entered into two contracts relevant to this inquiry. In 2003, he entered into a consulting agreement with AngioScore; under that agreement, Dr. Lotan assigned to AngioScore all his rights in inventions that he worked on, and which related to AngioScore's business, during the contract's term. (ECF No. 36-2 at 2-3.) AngioScore contends that Dr. Lotan thereby assigned to it all his rights in the subject patents. In June 2014, one day before TriReme filed this suit, Dr. Lotan granted TriReme an exclusive worldwide license to "exploit" his rights in those patents. (ECF No. 36-3 at 2-8.) Both contacts are more fully described below.

I. THE 2003 CONSULTING AGREEMENT

AngioScore entered into a consulting agreement with Dr. Lotan in November 2003, though the agreement had a retroactive effective date of May 1, 2003. (*See* ECF No. 36-2 at 2, 5.) The agreement's terms are undisputed. Under the contract, in exchange for AngioScore stock options,

[2] Because it disposes of this motion on standing, the court does not address the parties' indispensable-party arguments under Rule 19.

[3] The parties have a separate patent-infringement case pending in this district. *See AngioScore, Inc. v. TriReme Med., Inc.*, 4:12-cv-3393-YGR

Dr. Lotan agreed to "advise [AngioScore] on product design, clinical trial design and interpretation of clinical data," as well as "assist[ing AngioScore] with preclinical and clinical testing of the Company's products." (*Id.* at 2, 7.) The contract does not name a particular product. (*Id.*, *passim*.) He also agreed to the following assignment of rights:

> **Assignment of Inventions.** Consultant agrees to promptly disclose to the Company and hereby assigns to the Company, or its designee, ***all right***, title and interest in and to ***all inventions***, original works of authorship, developments, ***concepts***, know-how, improvements or trade secrets, ***whether or not patentable***, that Consultant may solely or jointly conceive or develop or reduce to practice during the term of this Agreement that relate to the Services (collectively referred to as "Inventions").

(*Id.* at 3, ¶ 9(b) (emphases added).) This assignment was subject to an exclusion or "carve-out" term, by which Dr. Lotan could identify and retain his interest in preexisting inventions, so that no interest in those "prior inventions" would be assigned to AngioScore. The carve-out provided:

> **Inventions Retained and Licensed.** Consultant has attached hereto, as part of Exhibit C, a list describing all ***inventions, original works of authorship, developments, improvements***, and trade secrets which were made by Consultant prior to the date of this Agreement (collectively referred to as "Prior Inventions"), that belong solely to Consultant or belong to Consultant jointly with another and that relate to any of the Company's current or proposed businesses, products or research and development; or if no such list is attached, ***Consultant represents that there are no such Prior Inventions***. If, in the course of providing the Services, Consultant incorporates into a Company product, process or machine or into any Invention (as defined below), a Prior Invention owned by Consultant or in which Consultant has an interest, the Company is hereby granted and shall have a non-exclusive royalty-free, irrevocable, perpetual, worldwide license (with the right to sublicense) to make, have made, copy, modify, make derivative works of, use, sell and otherwise distribute such Prior Inventions as part of or in connection with such product, process, machine or Invention.

(*Id.* at 3, ¶ 9(a) (underlines in original) (italics added).) Dr. Lotan signed Exhibit C but, leaving the available space blank, did not list any "Prior Inventions." (*Id.* at 8.)

II. DR. LOTAN'S WORK ON THE BALLOON CATHETER

Dr. Lotan's early work on the catheter is to a point undisputed. In April 2003, working alongside then AngioScore representatives, Dr. Konstantino and Mr. Feld, Dr. Lotan conducted an animal study in which he inserted prototype catheters into the blood vessels of an unfortunate pig. (*E.g.*, ECF No. 36 at 10-11; ECF No. 37 at 10-13.) For present purposes, the prototype catheter

had two salient features: a balloon and a "metal scoring element" that wrapped around the balloon's outside. (ECF No. 36 at 8-9.) The uninflated device would be "snaked through" a patient's (or a pig's) blood vessels. (*Id.* at 8.) Once it reached the target plaque inside the vessels, "the balloon would be inflated and press itself and the metal on top of the balloon into the plaque, thereby moving and compressing the plaque to increase the diameter of the opening in the circulatory system and improve blood flow." (*Id.* at 8.) The balloon would then be deflated, with the metal element returning "to roughly its original configuration," so that it could be safely "snaked back out of the circulatory system." (*Id.* at 9.)

The pig study revealed a problem: in several attempts, in retracting the prototype device, the metal element detached from the balloon. This made removing the catheter difficult. (ECF No. 36-7 at 2-6.) In some cases the metal element was left behind entirely. (*Id.*) Within the next few days, Dr. Lotan's lab wrote a report memorializing the results of the pig study. (*Id.*; *see* ECF No. 36-4 at 56-59, 80-83.) The report noted the problem with the metal detaching and made several "recommendations" — at least some of which Dr. Lotan claims were his. (*See* ECF No. 36-4 at 56-59; ECF No. 36-7 at 2-6.) In short, the report suggested that both ends of the metal element be fastened to the balloon. (The prototype had featured one fixed and one free-floating end.) At the same time, this bond had to be flexible enough to allow the balloon to deflate and the wire to return to its original position, thus enabling the device to be removed safely. (*See id.*; ECF No. 36-4 at 26.) The study participants (including Dr. Lotan) shared one email and had two meetings about the bonding issue, all in April 2003. (Lotan Dep. – ECF No. 37-2 at 57-58; ECF No. 37-8; ECF No. 37-15, ¶¶ 9-11.)

The parties disagree over what, if anything, Dr. Lotan did in connection with the balloon catheter after the April 2003 pig study. TriReme contends that Dr. Lotan made no further contribution. (*See, e.g.*, ECF No. 37 at 17-21.) With the April 2003 study and report, in TriReme's view, Dr. Lotan's contribution to developing the catheter was "complete[]." (*Id.*) AngioScore responds that Dr. Lotan continued to work on issues related to the catheter, and did so under the 2003 consulting agreement. (*E.g.*, ECF No. 38 at 13-14.)

The evidence on Dr. Lotan's post-April 2003 work is as follows. There is no dispute that, after

April 2003, Dr. Lotan did not work on the physical design of the catheter. After that date, as Dr. Lotan recounts matters, product design was turned over to AngioScore's engineers. (*See* ECF No. 36-4 at 20-21, 96-98, 147-48.) Dr. Lotan also testified, though, that after April 2003 he continued to work on other catheter-related issues under the terms of his consulting contract with AngioScore. (ECF No. 36-4 at 53-56, 74-75, 125-27.) He relates "talking" with AngioScore and "plann[ing] on human studies" for the catheter in the summer of 2003. (*Id.* at 75.) Some of these studies did not come to pass; some did. (*Id.* at 74-75.) Dr. Lotan not only helped "design[]" some of these human trials (*id.* at 53-55); he personally conducted some of them (*id.* at 125-27). He also testified that he was involved in the "interpretation of [this] clinical data" under the consulting agreement. (*Id.* at 54.)

III. DR. LOTAN'S 2014 LICENSE TO TRIREME

Over the next decade, Dr. Lotan's relationship with AngioScore deteriorated; he could describe himself by late 2013 as being "furious" with the company. (Lotan Dep. – ECF No. 36-4 at 5.) He learned at that time that his AngioScore options had expired; the company's board reissued them, but at a price that, according to Dr. Lotan, made them "much less [valuable] than they really were." (*Id.* at 6.) Months later, believing that he had rights in the subject patents, Dr. Lotan discussed licensing them with TriReme. (*See id.* at 28-29.) In June 2014, Dr. Lotan entered into a contract with TriReme, under which he granted TriReme a license "to exploit the Lotan IP rights" — meaning, whatever rights Dr. Lotan had in the patents in suit. (*Id.* at 28-29; Licensing Agreement – ECF No. 36-3 at 2-3.) Dr. Lotan testified that, as he understands it, he has granted TriReme only a license, and that he, Dr. Lotan, continues to own his inventor's rights in the subject patents. (ECF No. 36-4 at 30.)

GOVERNING LAW

TriReme brings this case under 35 U.S.C. § 256 to add Dr. Lotan as a named inventor of the patents in suit. (*See, e.g.*, ECF No. 1 at 1, 6.) A party invoking § 256 must satisfy constitutional standing requirements. *Larson v. Correct Craft, Inc.*, 568 F.3d 1319, 1325-27 (Fed. Cir. 2009); *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1357 (Fed. Cir. 2001). "That is, the party must demonstrate that he has 'suffered an injury-in-fact, that the injury is traceable to the conduct

complained of, and that the injury is redressable by a favorable decision.'" *Informatics Applications Grp., Inc. v. Shkolnikov*, 836 F. Supp. 2d 400, 411 (E.D. Va. 2011) (citing *Chou*, 254 F.3d at 1357) (citing in turn U.S. Const. art. III, § 2 and *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). To have standing under § 256, a party must assert either "expected ownership rights in the patent at issue" or a "concrete financial interest in the patent, albeit an interest less than ownership." *Shkolnikov*, 836 F. Supp. 2d at 411 (quoting in part *Chou*, 254 F.3d at 1358-59). One who assigns away his rights in a patent lacks § 256 standing. *See Larson*, 569 F.3d at 1326-27; *see also Jim Arnold Corp. v. Hydrotech Sys., Inc.*, 109 F.3d 1567, 1571-75 (Fed. Cir. 1997) (patent-infringement suit) (discussed in *Larson*).

ANALYSIS

The court holds that Dr. Lotan assigned whatever rights he had in the subject patents to AngioScore in 2003. He had no rights in those patents to license to TriReme in 2014. TriReme thus has no actionable interest in those patents and no standing to pursue a § 256 claim to correct inventorship on the patents.

I. DR. LOTAN ASSIGNED HIS RIGHTS TO ANGIOSCORE IN 2003

A. Basic Contractual Analysis

The parties' primary analytical dispute centers on whether Dr. Lotan completed his inventive contributions to the catheter before the May 1, 2003 effective date of his consulting agreement, or whether he continued to work after that date. TriReme contends (in sum) that Dr. Lotan's work — consisting of the April 2003 pig study and report — was "complete" before May 1, 2003; that, although that work entitles him to inventorship under patent law, it did not constitute a "Prior Invention" under the consulting agreement; and thus that he should be added to the subject patents as an inventor. AngioScore responds, first, that Dr. Lotan's work continued after May 1, 2003, so that any rights he had in the catheter were assigned under paragraph 9(b) of his consulting agreement. Second, and maybe more operatively, AngioScore argues that it is ultimately immaterial whether his work continued after May 1, 2003 or not; either way, because he did not list the April 2003 pig study (along with his subsequent report and recommendations) as a "Prior Invention" under the consulting agreement, Dr. Lotan failed to retain any rights growing out of

that study, and assigned all his interest in the catheter to AngioScore. (*See* ECF No. 38 at 4-8.) In AngioScore's view, Dr. Lotan had nothing to license to TriReme in 2014 and TriReme thus lacks standing to pursue a § 256 claim.

The court agrees with AngioScore. The question of when Dr. Lotan completed work is ultimately immaterial: Even if his work was complete before May 1, 2003, under the express terms of the consulting agreement, he assigned all rights in the catheter to AngioScore and certified that there were no earlier inventions in which he was retaining an interest.

This conclusion follows from a straightforward application of the consulting agreement. Under that agreement, Dr. Lotan agreed to provide AngioScore with consulting "Services." Those services were defined as follows: "Consultant shall advise Company on product design, clinical trial design and interpretation of clinical data. Consultant shall assist company with preclinical and clinical testing of the Company's products . . . ." (ECF No. 36-2 at 2, 6.) There is no dispute that the catheter was an AngioScore "product." In the contract's pivotal term, Dr. Lotan assigned to AngioScore

> all right, title and interest in and to all inventions, original works of authorship, developments, concepts, know-how, improvements or trade secrets, whether or not patentable, that Consultant may solely or jointly conceive or develop or reduce to practice during the term of this Agreement that relate to the Services (collectively referred to as "Inventions").

(*Id.* at 3, ¶ 9(b) (underline in original).) The agreement also provided the following "carve-out," under which Dr. Lotan could identify and retain (*i.e.*, not assign to AngioScore) his rights in any preexisting work:

> **Inventions Retained and Licensed.** Consultant has attached hereto, as part of Exhibit C, a list describing all ***inventions, original works of authorship, developments, improvements***, and trade secrets which were made by Consultant prior to the date of this Agreement (collectively referred to as "Prior Inventions"), that belong solely to Consultant or belong to Consultant jointly with another and that relate to any of the Company's current or proposed businesses, products or research and development; or ***if no such list is attached, Consultant represents that there are no such Prior Inventions.*** If, in the course of providing the Services, Consultant incorporates into a Company product, process or machine or into any Invention (as defined below), a Prior Invention owned by Consultant or in which Consultant has an interest, the Company is hereby granted and shall have a non-exclusive royalty-free, irrevocable, perpetual, worldwide license (with the right to sublicense) to make, have made, copy, modify, make derivative works of, use, sell and otherwise distribute

> such Prior Inventions as part of or in connection with such product, process, machine or Invention.

(*Id.* at 3, ¶ 9(a) (underlines in original) (boldface and italics added).) Again, Dr. Lotan signed Exhibit C but did not list any "Prior Inventions." (*Id.* at 8.) He thus "represent[ed] that there [were] no such Prior Inventions."

From these undisputed points it would seem to follow that Dr. Lotan assigned whatever rights he had in the balloon catheter to AngioScore in 2003, retained nothing through the exclusion mechanism of paragraph 9(a), and so had nothing to license to TriReme in 2014. This conclusion is, as AngioScore rightly observes, independent of whether Dr. Lotan completed his inventive contributions to the catheter before or after the consulting agreement's effective date of May 1, 2003. Even if, as TriReme argues, Dr. Lotan completed his work by May 1, 2003, he still represented that there were no "Prior Inventions," as the consulting agreement defined that term, in which he was "retain[ing]" an interest.

B. TriReme's Arguments

TriReme offers several arguments against that conclusion. The court has weighed them all carefully, but finds none of them convincing.

1. The exclusion term does not cover only "formal" inventions

First, TriReme argues that by "Prior Inventions" the carve-out meant only complete inventions; that is, only "formal inventions already made, such as patents and patent applications." (ECF No. 38 at 19-20.) Dr. Lotan did not consider his April 2003 work to constitute a "formal invention[]" and so did not list them in the carve-out's Exhibit C. (*Id.* at 20 and n. 2.) His pre-May 1, 2003 work entitled him to inventor status under the patent law, TriReme argues, and thus to a § 256 correction; but that work did not itself rise to the level of a "formal invention" and so did not need to be listed on Exhibit C to be saved from assignment.

The express language of the consulting agreement precludes this argument. What TriReme insists upon, in other words, is not what the contract says. Paragraph 9(a) does not say that Dr. Lotan should list only complete and "formal inventions." It defined "Prior Inventions" as "all inventions, *original works of authorship, developments, improvements*, and trade secrets which were made by Consultant prior to the date of this Agreement . . . ." (ECF No. 36-2 at 3, ¶ 9(a)

(emphasis added).) The April 2003 study, as well as Dr. Lotan's report on that study and his "recommendations" for addressing the problem with the metal element detaching from the prototype catheter: these all fall within the plain meaning of the terms, "works of authorship, developments, [or] improvements." The agreement required Dr. Lotan to list such work in Exhibit C, if he was going to retain any rights in them, or (at most) license them to AngioScore for use in the catheter. To interpret this language as meaning only complete "inventions" would require the court to ignore the other terms — "works of authorship, developments, improvements" — and to treat these as surplus nullities. Such interpretations are disfavored. *See* Cal. Civ. Code § 1641 ("The whole of a contract is to be taken together, so as to give effect to every part, if reasonably practicable . . . .") The agreement further said, again in plain language, that if no such material was listed, then Dr. Lotan represented that there was no such work. If Dr. Lotan obtained rights in the catheter as a result of his pre-May 1, 2003 work — even if that work did not itself constitute a full-blown "formal invention" — he did not save those rights from being assigned to AngioScore.

2. The "Prior Inventions" term does not merely grant a license

Second, TriReme argues that the carve-out of paragraph 9(a) "at most . . . conveys to AngioScore a non-exclusive license to Prior Inventions . . . ." (ECF No. 37 at 19.) TriReme rests this argument on the title of the provision ("Inventions Retained and Licensed") and on the fact that the second segment of this provision grants AngioScore a non-exclusive license in any "Prior Inventions" that are incorporated into the company's products. (*See* ECF No. 36-2 at 3, ¶ 9(a).)

But this argument, too, quickens only by mangling the express terms of the consulting agreement and unraveling its manifest intent. First, the argument proceeds as if paragraph 9(a) addresses only licensing, when by its terms it address "Prior Inventions" that are both "retained" and "licensed." The fact that some Prior Inventions may be licensed does not rule out the possibility that some may be retained completely. Perhaps more substantively, TriReme offers an unacceptable reading of this contract term. The first part of paragraph 9(a), again, defines "Prior Inventions" and directs Dr. Lotan to list these on Exhibit C to retain them. The second part of paragraph 9(a) then says that, if any "Prior Inventions" are incorporated into an AngioScore product, then the company has a certain license to them. But this depends on there being Prior

Inventions in the first place. And, because he did not list any such inventions on Exhibit C, Dr. Lotan represented that there were none.

3. The standing analysis is not too "intertwined" with the merits

Third, TriReme contends that the court should not rule on the motion to dismiss because "jurisdictional and substantive issues are inextricably intertwined." (ECF No. 37 at 22.) TriReme continues: "Jurisdictional finding of genuinely disputed facts is inappropriate when the jurisdictional issue and substantive issues are so intertwined that the question of jurisdiction is dependent on the resolution of factual issues going to the merits of an action." (*Id.* (quoting *Sun Valley Gasoline, Inc. v. Ernst Enters., Inc.*, 711 F.2d 138, 139 (9th Cir. 1983)). TriReme contends that the "nature and timing" of Dr. Lotan's contribution to the catheter — whether he made an inventive contribution before May 1, 2003 that would entitle him to inventor status — is a central merits issue that overlaps the jurisdictional determination and thus prevents the court from ruling on standing. (ECF No. 37 at 22.)

The court disagrees. It goes without saying that subject-matter jurisdiction is a fundamental concern for a federal court. Without such jurisdiction, the court has no power to proceed. The court does not think that this case involves jurisdictional and merits issues that are so "intertwined" as to prevent the normal, primary resolution of jurisdiction. To the contrary. The facts that touch upon jurisdiction — even if they overlap to some degree with merits issues related to the nature of Dr. Lotan's inventive contribution — are nevertheless so basic that they permit resolution of the standing issue now. The jurisdictional decision here requires little more than a straightforward reading of the consulting agreement in light of the most preliminary facts. In this respect, this case is like the patent-correction and –infringement decisions in, for example, *Larson*, or *Jim Arnold*, where the Federal Circuit considered contractual assignments in light of equally basic facts to decide that plaintiffs lacked standing under either § 256 (*Larson*) or other parts of patent law. *See IMATEC, Ltd. v. Apple Computer, Inc.*, 15 F. App'x 887, 892 (Fed. Cir. 2001) (affirming standing dismissal of infringement claim where jurisdictional holding "turn[ed] on the proper construction of [an] assignment agreement").

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4. TriReme carves up the contract and so loses its whole purpose

Finally, the court addresses TriReme's broadest argument and basic approach to interpreting the 2003 consulting agreement. At the hearing on AngioScore's motion to dismiss, TriReme's counsel suggested that the court may be misunderstanding the contract. There are, counsel emphasized, two distinct terms in issue: the "Inventions Retained and Licensed" term of paragraph 9(a); and the main assignment clause of paragraph 9(b). Only the latter deals with assignments. No assignment can follow from the "Inventions Retained" provision of paragraph 9(a). Indeed, under TriReme's view, paragraph 9(a) ultimately has no effect. That paragraph addressed only full-blown, "formal" inventions; because Dr. Lotan's pre-May 1, 2003 work did not constitute such a complete invention, there was nothing for him to list as a "Prior Invention" under paragraph 9(a). In sum — and TriReme surely phrased it better — if we accept the rest of TriReme's arguments, then Dr. Lotan did no work after May 1, 2003 that could have been assigned to AngioScore under paragraph 9(b), and there was no "Prior Invention" for Dr. Lotan to retain under paragraph 9(a). Whatever rights Dr. Lotan gained from his April 2003 work remained with him to license to TriReme in 2014. Counsel urged that this conclusion followed from a due insistence on closely tracking the language of the consulting agreement.

The court has weighed this argument carefully. It concludes, however, that it is TriReme that misreads the contract. More precisely, TriReme hyper-parses the contract, walling off terms that must be read together. This leads TriReme to betray what the agreement's plain language reveals to be its objectively apparent purpose.

It will help to recall some rudiments of contract interpretation. The Federal Circuit tells us that California law controls the inquiry: "Construction of patent[-]assignment agreements is a matter of state contract law." *Preston v. Marathon Oil Co.*, 684 F.3d 1276, 1285 (Fed. Cir. 2012) (quoting *Euclid Chem Co. v. Vector Corrosion Techs., Inc.*, 561 F.3d 1340, 1343 (Fed. Cir. 1009)). "The fundamental goal of contractual interpretation is to give effect to the mutual intention of the parties." *Align Tech., Inc. v. Fed. Ins. Co.*, 673 F. Supp. 2d 957, 966 (N.D. Cal. 2009) (quoting *Bank of the West v. Superior Court*, 2 Cal.4th 1254, 1265 (1992)). "California recognizes the objective theory of contracts, under which it is *the objective intent, as evidenced by the words of*

the contract, rather than the subjective intent of one of the parties, that controls interpretation." *Cedars–Sinai Med. Ctr. v. Shewry*, 137 Cal. App. 4th 964, 980 (2006) (quoted in *Spacone v. Williamson*, 258 F. App'x 141(9th Cir. 2007) (mem.) (emphasis added)). "When a contract is reduced to writing, the intention of the parties is to be ascertained from the writing alone, if possible . . . ." Cal. Civ. Code § 1639. Furthermore: "The language of a contract is to govern its interpretation, if the language is clear and explicit, and does not involve an absurdity." Cal. Civ. Code § 1638. "Words in a contract which are *wholly inconsistent with its nature, or with the main intention of the parties*, are to be rejected." Cal. Civ. Code § 1653 (emphasis added). By short extension, and what is more important here, the court must equally reject proposed *interpretations* that are "wholly inconsistent" with a contract's "nature," or with the parties' (objectively apparent) "main intention." A final point will spotlight why TriReme's surgical approach does not persuade: "The whole of a contract is to be taken together, so as to give effect to every part, if reasonably practical, each clause helping to interpret the other." *Navarro v. Mukasey*, 518 F.3d 729, 734 (9th Cir. 2008) (applying California law); *see also, e.g.*, 4 S. Williston, *A Treatise on the Law of Contracts* § 618, at 710 (3d ed. 1961) ("A written contract must be read as a whole and every part interpreted with reference to the whole.").

Compartmentalizing contract terms that should instead be read together, TriReme's suggested approach and resulting interpretation parse too much; the plaintiff thereby both ignores the context that spawned the contract and thwarts the objectively apparent intent of the whole agreement. (Naming each letter, we will fail to read the word.) Consider the parties' description of Dr. Lotan's and AngioScore's circumstances in 2003. The parties dispute nothing in this respect. The parties who entered this agreement — Dr. Lotan on the one hand and, on the other, the few people who constituted AngioScore — were then a handful of people in a medical startup. Their one product-to-be — the thing on which they were all focused — was the catheter. The purpose of the consulting agreement's two salient clauses (paragraphs 9(a) and 9(b)) — and it is well to notice that these are subparagraphs of one larger section on "Inventions" — was to identify any preexisting work that Dr. Lotan was doing that might compete with the developing catheter, license such work to AngioScore if any was incorporated into the catheter, and otherwise to assign

to AngioScore whatever rights Dr. Lotan's work on the catheter might have given him. That purpose is apparent from the contract's plain language.[4] To reach TriReme's different conclusion, to find that Dr. Lotan somehow retained rights that he could later license to TriReme, goes beyond a fair reading of the contract into casuistic over-dissection. If we wall the two salient clauses off from one another, as TriReme urges, the intent of the whole contract falls between them and is lost. Furthermore, TriReme's analysis depends on at least one subsidiary argument that (as discussed above) is unacceptable: *i.e.*, the idea that the "Prior Inventions" term of paragraph 9(a) applies to only fully finalized, "formal" inventions. For these reasons, the court cannot accept TriReme's contractual analysis.

II. DR. LOTAN WORKED ON THE CATHETER AFTER MAY 1, 2003

Moreover, the May 1, 2003 consulting agreement is what compensated Dr. Lotan, defined his obligations (including confidentiality), and enabled his continued work on the catheter after May 1, 2003. Whatever rights he had in the catheter were thus assigned to AngioScore, apart from any consideration of the "Prior Inventions" exclusion, under the main assignment clause. That term, again, assigned to AngioScore "all right, title and interest in and to all inventions, original works of authorship, developments, concepts, know-how, [and] improvements . . . that Consultant may . . . *conceive or develop or reduce to practice* during the term of this Agreement that relate to the Services . . . ." (ECF No. 36-2 at 3, ¶ 9(b) (emphasis added).) Dr. Lotan testified that after April 2003 he continued to work on catheter-related issues under the terms of his consulting contract with AngioScore. (ECF No. 36-4 at 53-56, 74-75, 125-27.) He recounts "talking" with AngioScore and "plann[ing] on human studies" for the catheter in the summer of 2003. (*Id.* at 75.) Some of these studies did not come to pass; some did. (*Id.* at 74-75.) Dr. Lotan not only helped

[4] It is appropriate to consider the surrounding circumstances when assessing the meaning of this contract. California looks more readily than most states to "extrinsic evidence" in interpreting contracts. *See, e.g.*, *Monolithic Power Sys., Inc. v. Taiwan Sumida Elecs., Inc.*, 2006 WL 1530073, *2 (N.D. Cal. June 2, 2006) ("[I]n applying California law to contracts, courts often look to extrinsic evidence. California Code of Civil Procedure § 1856 provides that . . . *evidence of the circumstances under which the agreement was made*, or evidence to explain an extrinsic ambiguity *or otherwise interpret the terms of the agreement*, may be considered.") (emphases added) (internal quotation omitted).

"design[]" some of these human trials (*id.* at 53-55); he personally conducted some of them (*id.* at 125-27). He also testified that he was involved in the "interpretation of [this] clinical data" under the consulting agreement. (*Id.* at 54.) This is exactly the sort of work that his consulting agreement anticipates. (*See* ECF No. 36-2 at 6 (describing consulting services).) Again under the plain meaning of section 9(b)'s terms, this work might have amounted to (among other things) "developing," "improving," or "reducing to practice" the "recommendations" that Dr. Lotan made in April 2003 for improving the prototype catheter — and this is accepting TriReme's position that Dr. Lotan's contributions were included in the patented catheter.

At the hearing, TriReme argued that Dr. Lotan's work during the consulting agreement amounted to collecting regulatory data on a finished device. That may be true, yet it does not change the outcome. The court assumes that the inventive contribution was complete by April 2003 and does not need to consider the issue — which the parties did not fully brief — about when an idea penciled into a recommendation becomes an inventive idea. The point is only that purpose of the entire consulting agreement was to define the parties' obligations, enable Dr. Lotan's continued work on the only product at issue, and provide for his compensation.

III. ANALOGIES

The court thus concludes that Dr. Lotan assigned whatever interest he had in the balloon catheter to AngioScore in 2003. He had no rights in the catheter to license to TriReme in 2014. Consequently, TriReme has no interest in the patents-in-suit sufficient to support standing under § 256.

This conclusion is consistent with governing precedent. For example, this case is effectively identical to *Larson*, *supra*, in which the Federal Circuit held that an assignor-inventor had "no constitutional standing to sue for correction of inventorship" under § 256. *Larson*, 569 F.3d at 1325-27. The *Larson* plaintiff had assigned his rights in an invention to his employer under an employment contract. *Id.* at 1322. He later sued to be added as an inventor on the attendant patents. *Id.* at 1321-23. The district court granted summary judgment for the defendant and Larson appealed. *Id.* at 1322-23. Bypassing the summary-judgment issue, the Federal Circuit asked whether the plaintiff had sufficiently laid federal subject-matter jurisdiction. *Id.* at 1323. It held

that he had not. *Id.* at 1325-27. That court wrote: "Larson has affirmatively transferred title to the patents to [the defendant], and he stands to reap no benefit from a preexisting licensing or royalties arrangement." *Id.* at 1326. He thus had "no concrete financial interest" in the patents (*id.* at 1321); and, more precisely, "no financial interest in the patents sufficient for him to have standing to pursue a § 256 claim." *Id.* at 1326-27. The district court thus "lacked jurisdiction" to hear the § 256 challenge, and the appellate court directed that the case be remanded back to the Florida state court from which it had been removed. *Id.* at 1327-28.

In reaching this decision, the *Larson* court expressly drew on its "similar" decision in *Jim Arnold, supra*. *Larson*, 569 F.3d at 1327. In *Jim Arnold*, an inventor sued for patent infringement. Like Dr. Lotan, though, he had already "assigned away all his . . . rights" and thus had "no ownership interest" in the subject patents. *Id.* at 1327 (discussing *Jim Arnold*, 109 F.3d at 1571-72). The *Jim Arnold* court too held, consequently, that "the plaintiff lacked standing to pursue his infringement claim." *See Jim Arnold*, 109 F.3d at 1572. "Although *Jim Arnold* involved an infringement claim rather than an action to correct inventorship, the reasoning of that case nonetheless applies" to § 256 claims. *Larson*, 569 F.3d at 1327.

Finally, the decision in *IMATEC, Ltd. v. Apple Computer, Inc.*, 15 F. App'x 887 (Fed. Cir. 2001) further compels the conclusion that TriReme lacks constitutional standing to bring a § 256 claim. The undisputed inventor of several video-imaging patents there sued Apple for infringing on those patents. *Id.* at 888-90. The district court granted summary judgment for the defendant, based on a lack of constitutional standing, and the Federal Circuit affirmed. Like Dr. Lotan, the *IMATEC* inventor had previously assigned away his rights in the patents to the employer he was working for when he developed them. *Id.* at 889-90. The employment contract in *IMATEC* had provided a place for the plaintiff to exclude specified inventions from the assignment; but the district court concluded that the patents-in-suit were not among those that the plaintiff had listed for exclusion. *Id.* The appellate court upheld this determination. It also upheld the follow-on jurisdictional conclusion that, because the plaintiff had "assigned his rights to the patented inventions," he "lacked standing to bring [an] infringement suit." *Id.* at 893-96. The Federal Circuit's decision in *Preston v. Marathon Oil Co.*, 684 F.3d 1276, 1285 (Fed. Cir. 2012), though

different in details, is to the same ultimate effect.

CONCLUSION

Because Dr. Lotan assigned whatever rights he had in the patents-in-suit to AngioScore under the terms of the 2003 consulting agreement, he had no rights in those patents to license to TriReme in 2014. TriReme has no interest in the patents sufficient to give it constitutional standing to pursue a claim for correction of inventorship on those patents under 35 U.S.C § 256. The court therefore grants AngioScore's motion to dismiss and dismisses this case with prejudice.

This disposes of ECF No. 36.

IT IS SO ORDERED.

Dated: March 17, 2015

LAUREL BEELER
United States Magistrate Judge

United States District Court
Northern District of California

US008080026B2

(12) **United States Patent**
Konstantino et al.

(10) **Patent No.: US 8,080,026 B2**
(45) **Date of Patent: Dec. 20, 2011**

(54) **APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS**

(75) Inventors: **Eitan Konstantino**, Orinda, CA (US); **Tanhum Feld**, Moshav Merhavya (IL); **Nimrod Tzori**, Sunnyvale, CA (US)

(73) Assignee: **AngioScore, Inc.**, Fremont, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1967 days.

(21) Appl. No.: **10/917,917**

(22) Filed: **Aug. 13, 2004**

(65) **Prior Publication Data**

US 2005/0021071 A1 Jan. 27, 2005

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/810,330, filed on Mar. 25, 2004, now Pat. No. 7,955,350, which is a continuation-in-part of application No. 10/631,499, filed on Jul. 30, 2003, now Pat. No. 7,686,824.

(60) Provisional application No. 60/442,161, filed on Jan. 21, 2003.

(51) **Int. Cl.**
A61B 17/22 (2006.01)

(52) **U.S. Cl.** **606/159**; 623/1.11

(58) **Field of Classification Search** 606/159, 606/194; 604/22, 500; 623/1.11
See application file for complete search history.

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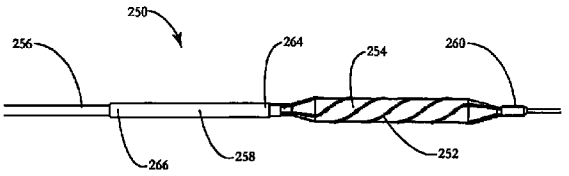
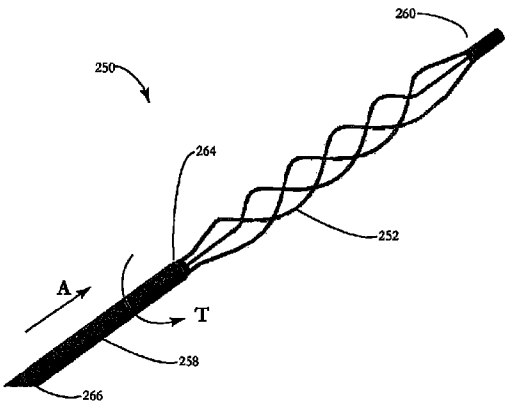
Primary Examiner — Victor Nguyen
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

An angioplasty catheter comprises a catheter body having a balloon or other radially expandable shell at its distal end. A non-axial external structure is carried over the shell and scores a stenosed region in a blood vessel when the balloon is inflated therein. The catheter has an attachment structure disposed between the catheter body and the balloon to accommodate foreshortening and rotation of the external structure as the balloon is expanded. The external structure may be part of a helical cage structure which floats over the balloon.

49 Claims, 15 Drawing Sheets





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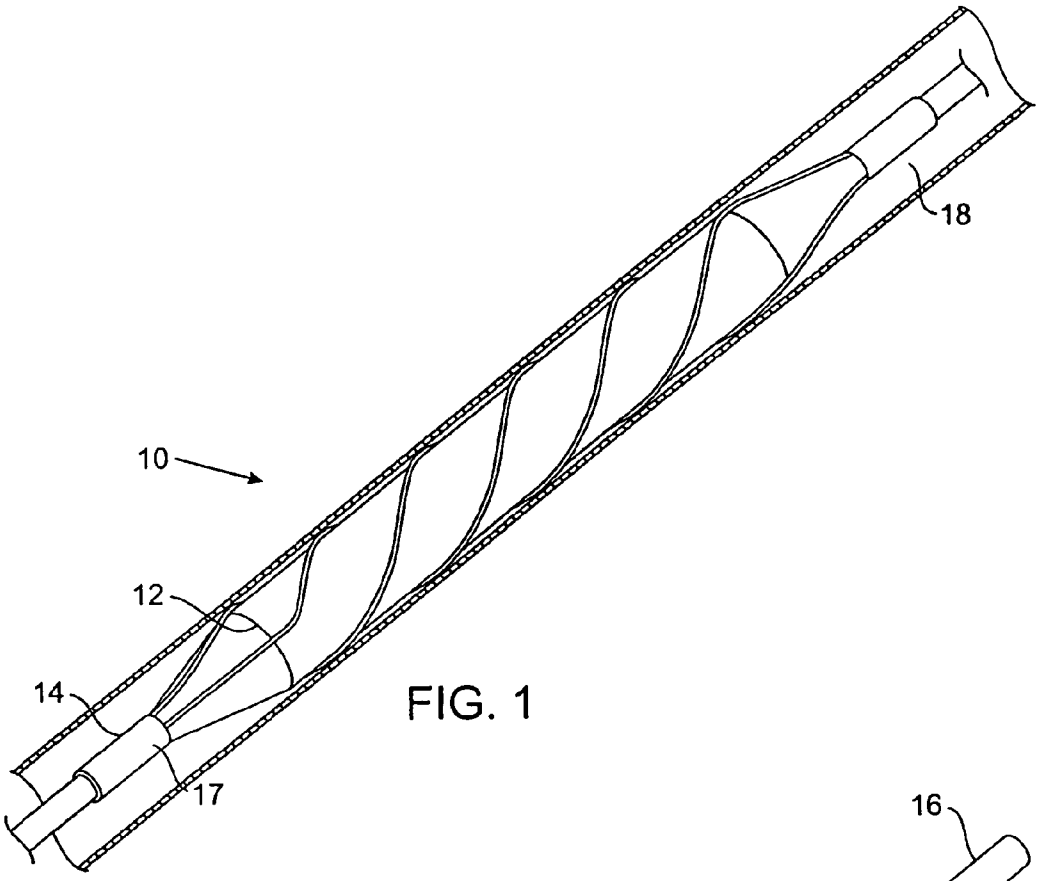

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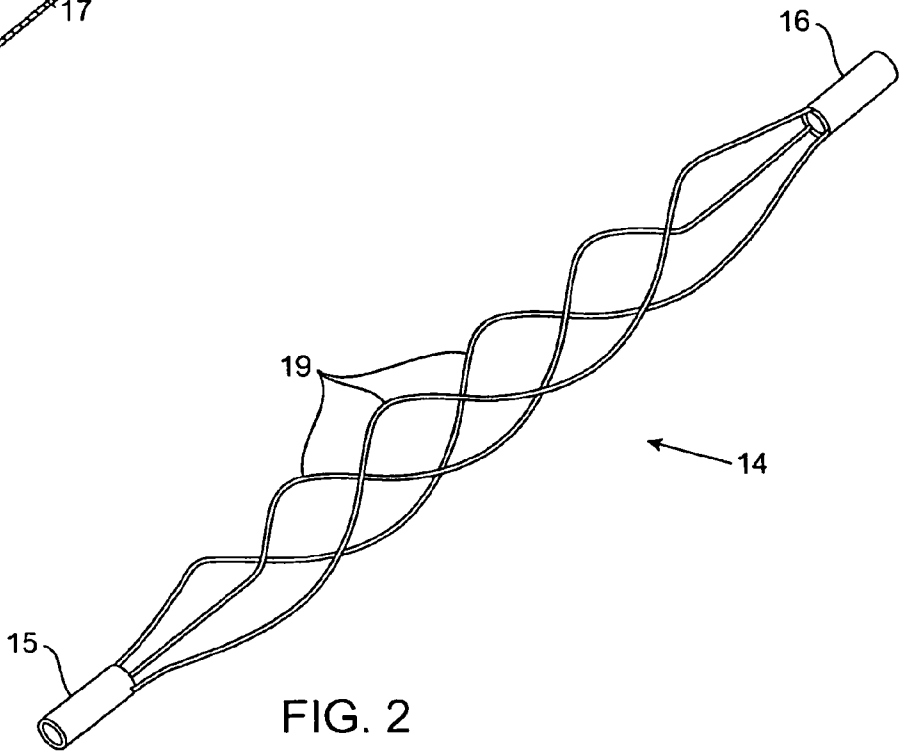


FIG. 2

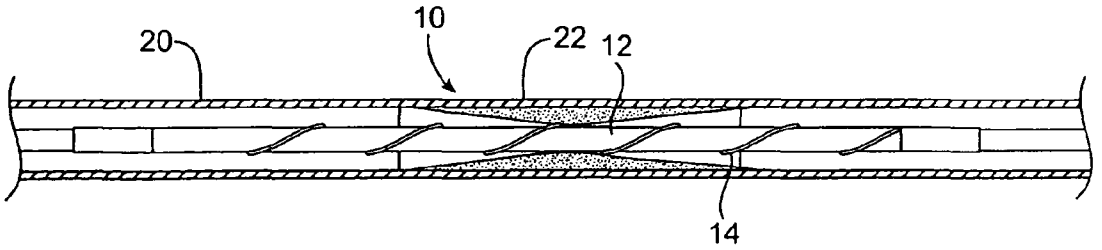
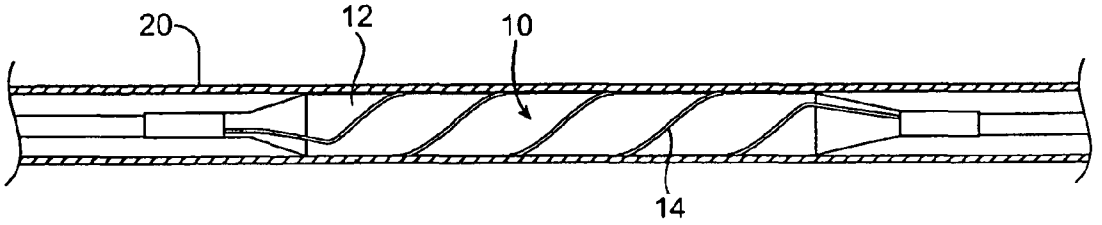


FIG. 1A



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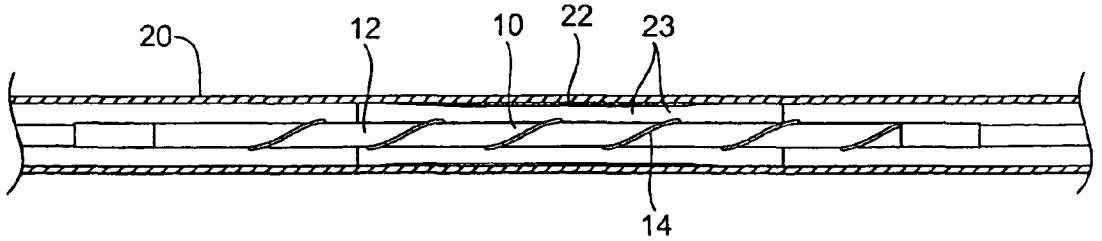


FIG. 1C

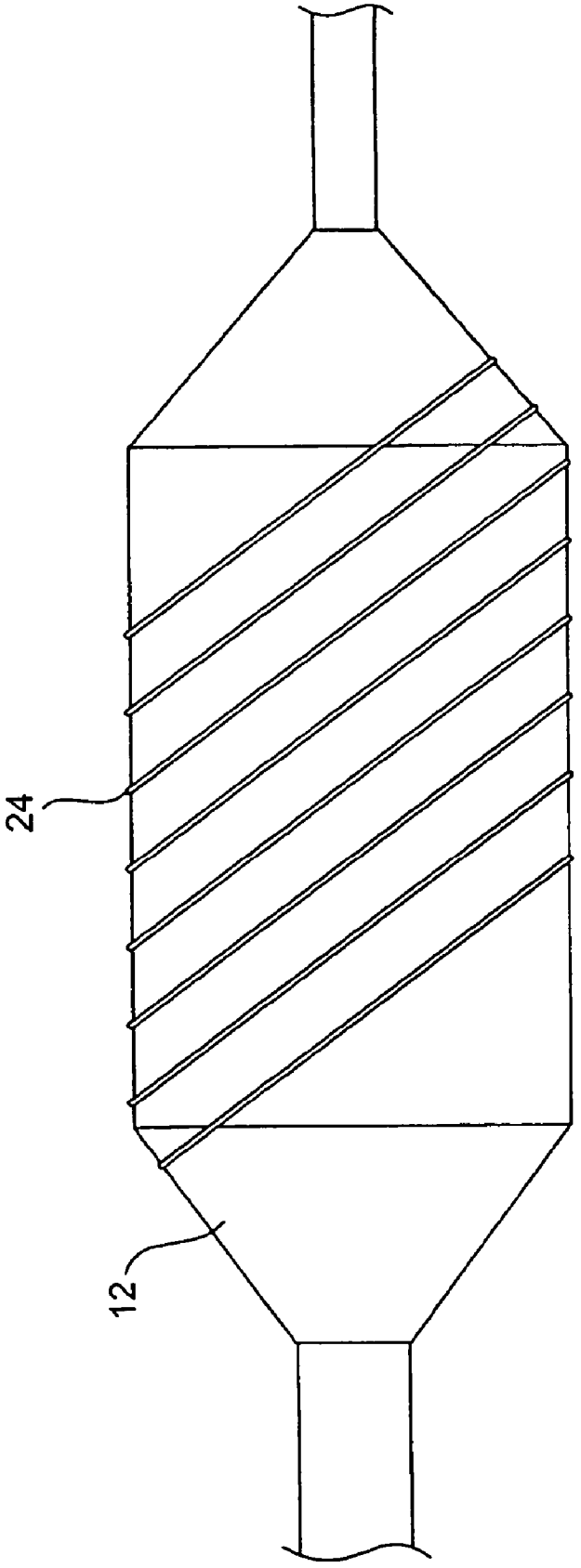


FIG. 3

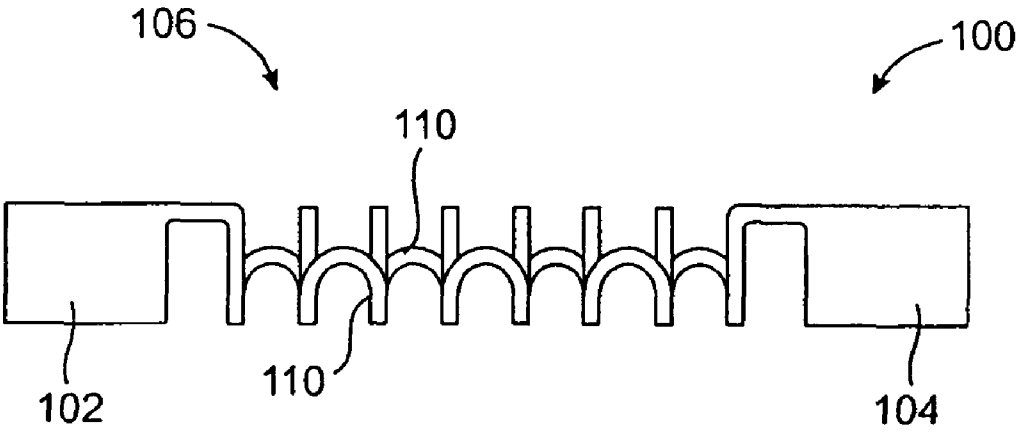
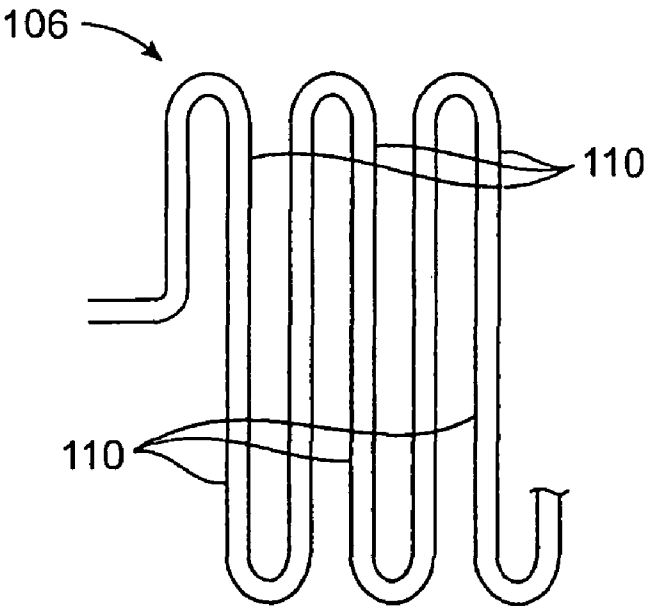


FIG. 4



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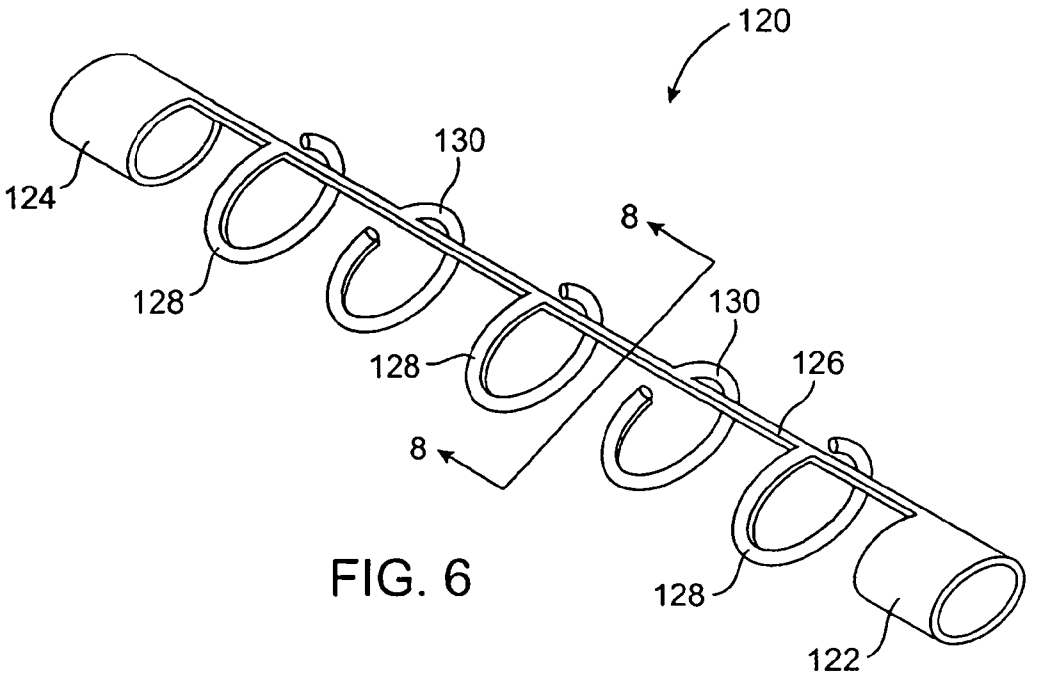

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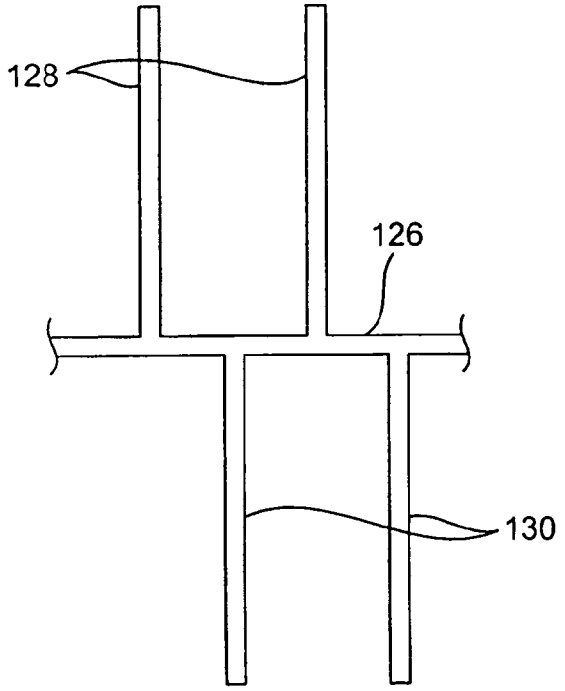


FIG. 7

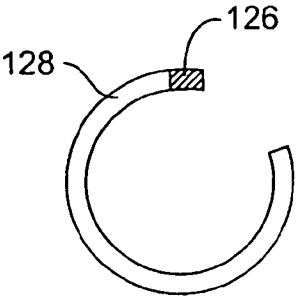


FIG. 8

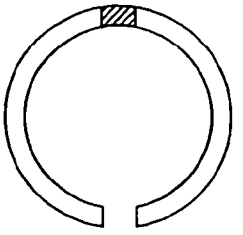


FIG. 9

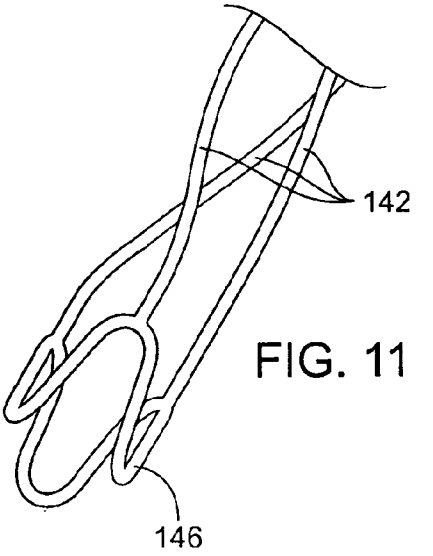


FIG. 11

FIG. 10

FIG. 12

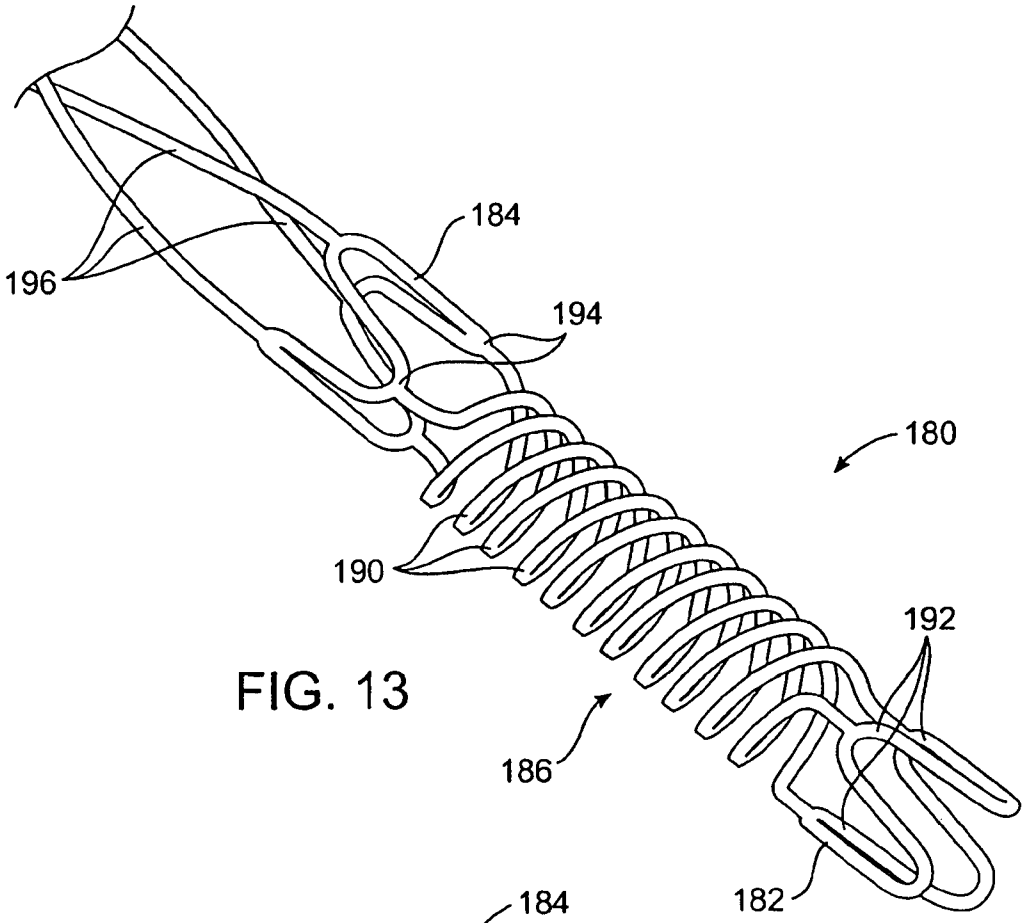


FIG. 13

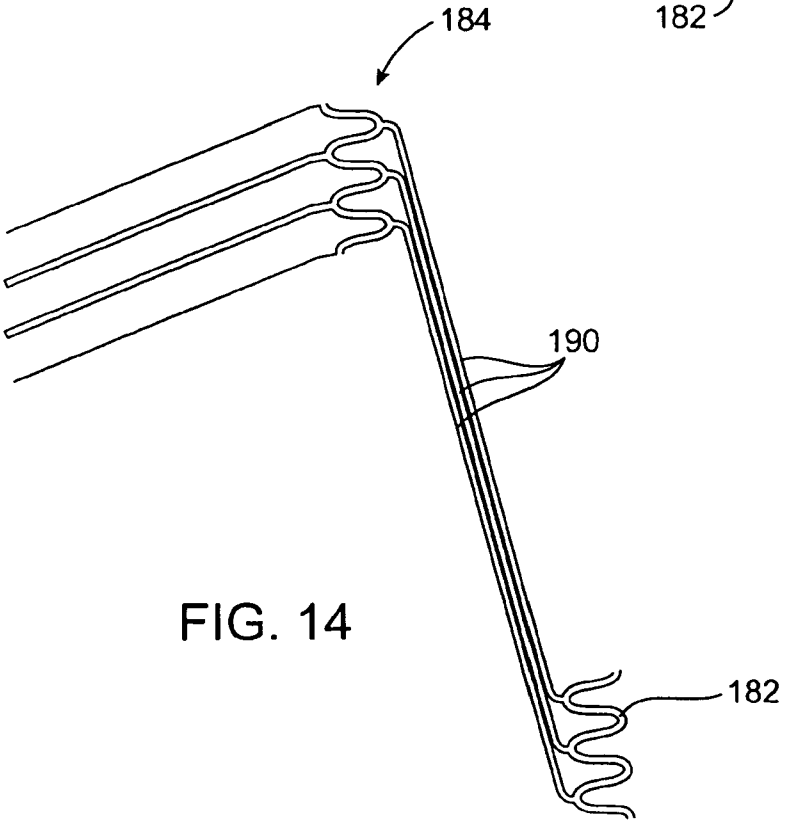


FIG. 14

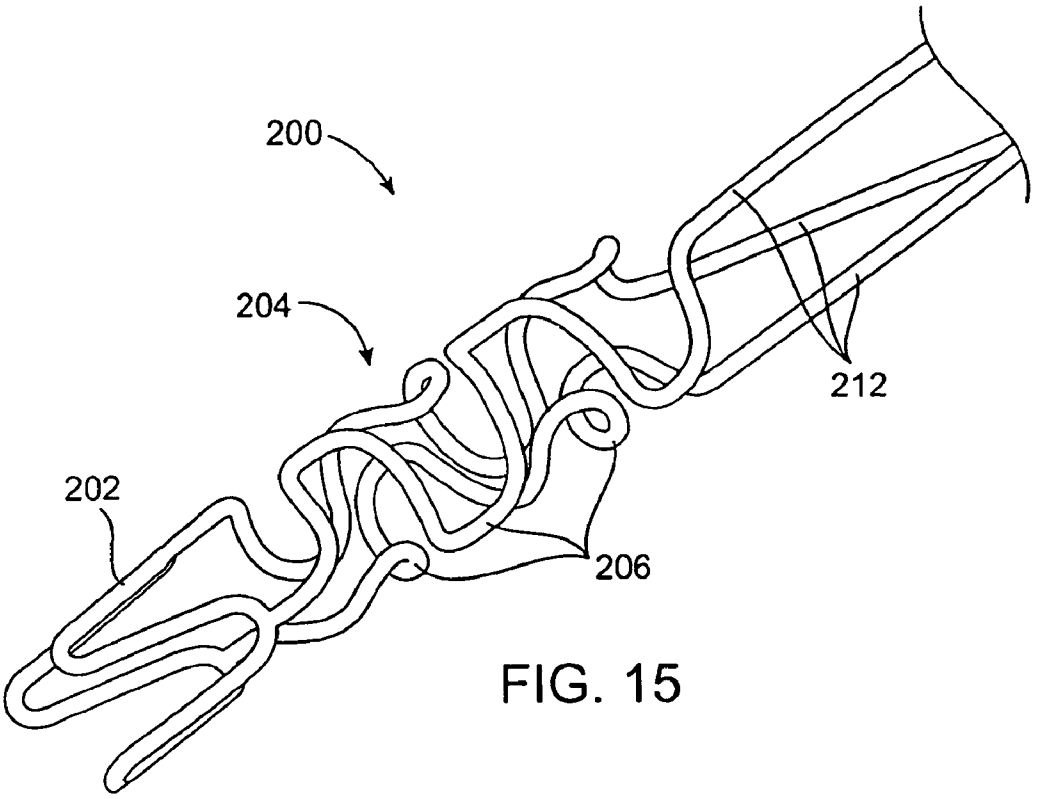


FIG. 15

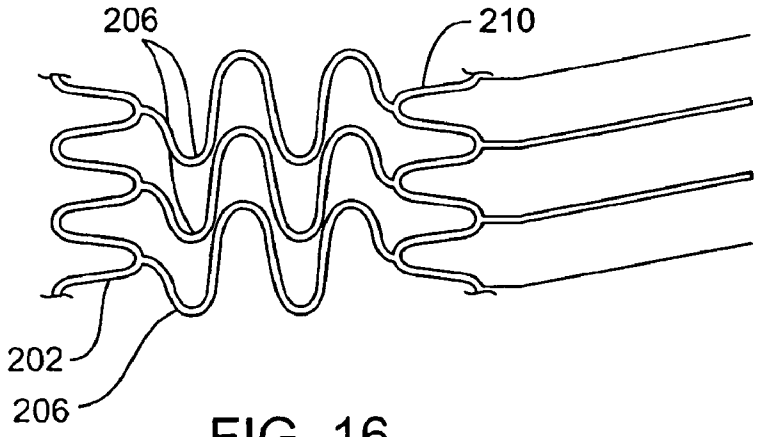


FIG. 16

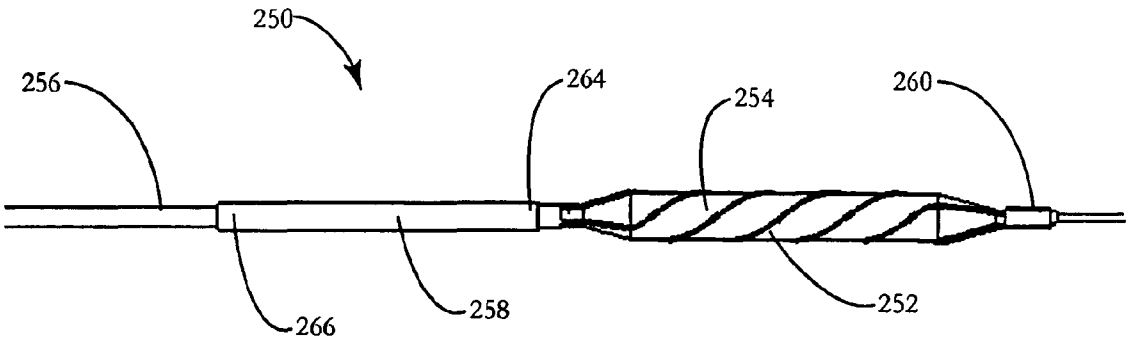


Fig. 17a

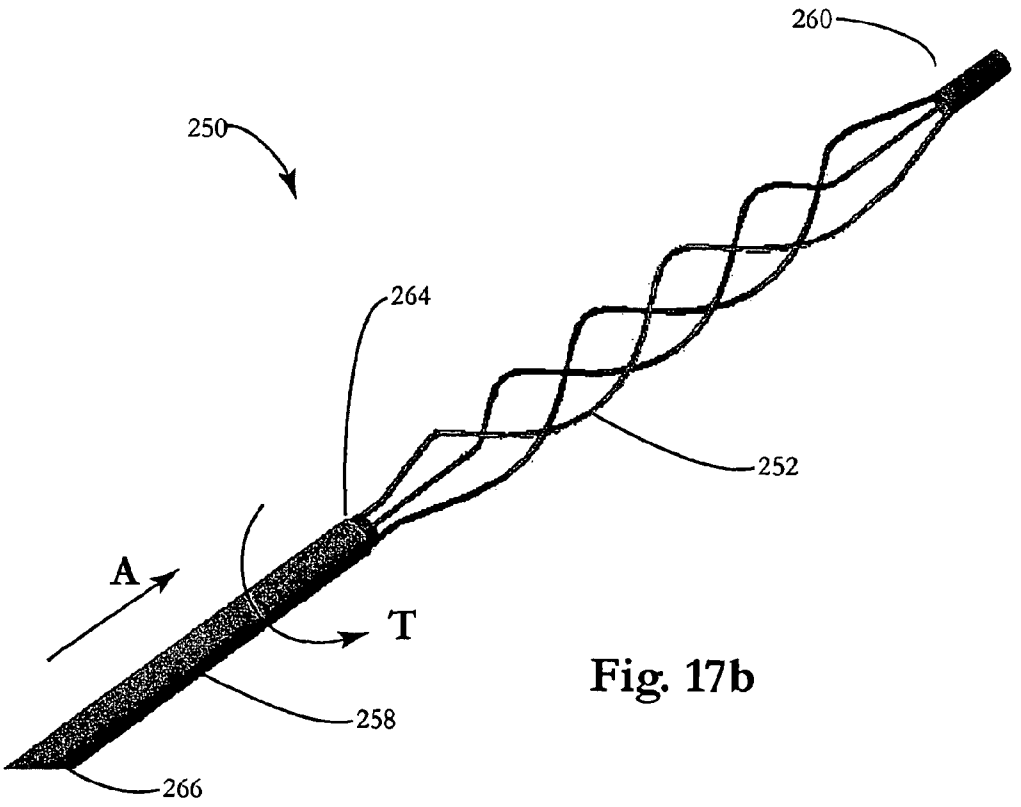


Fig. 17b

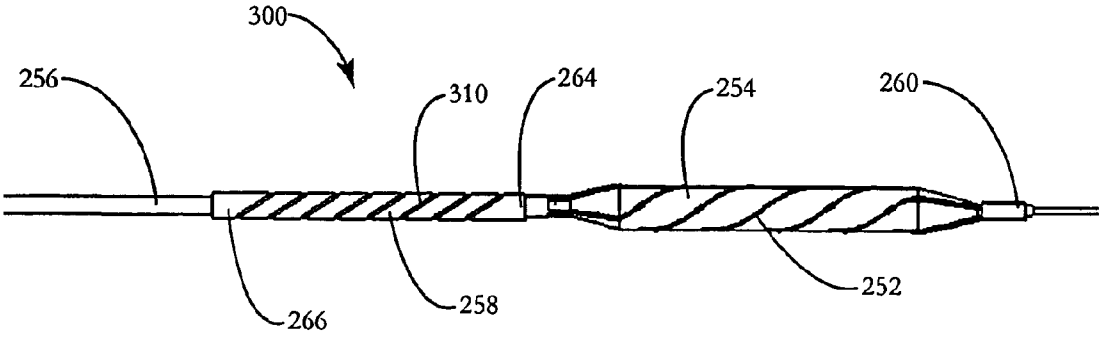


Fig. 18a

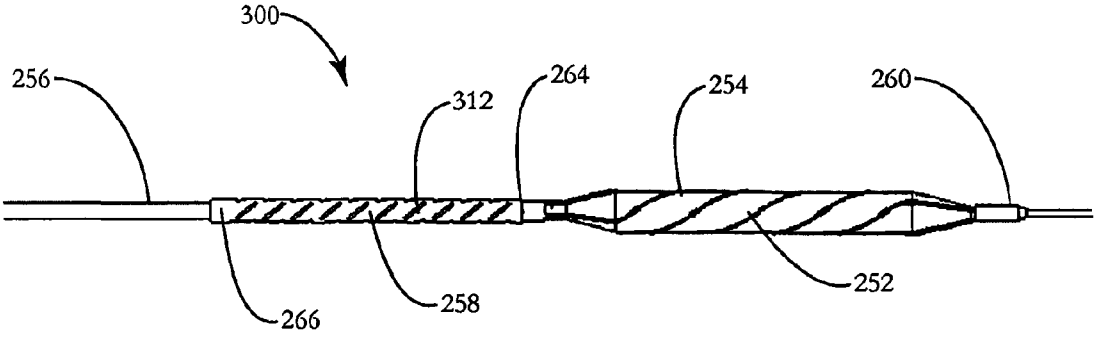


Fig. 18b

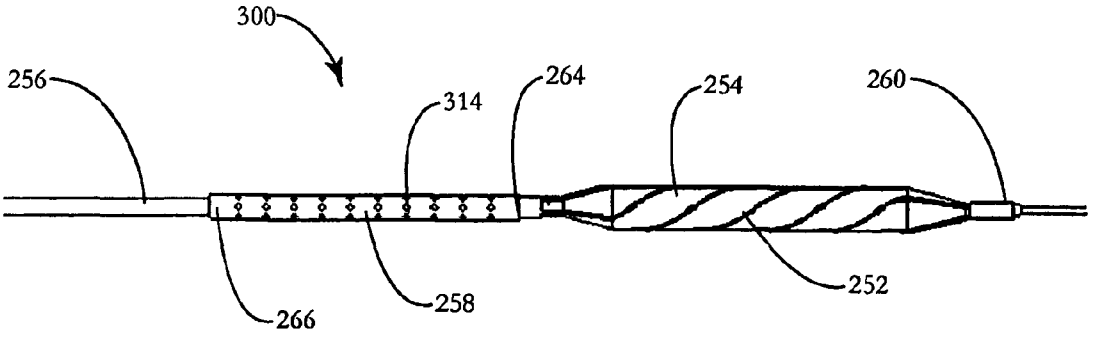
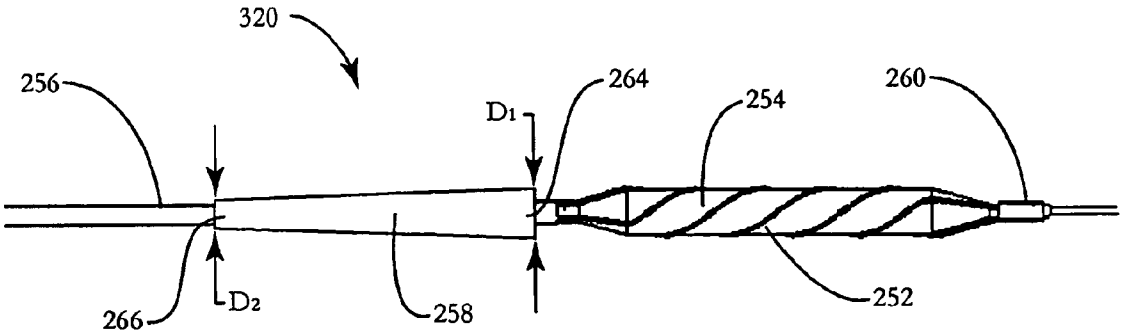


Fig. 18c


320
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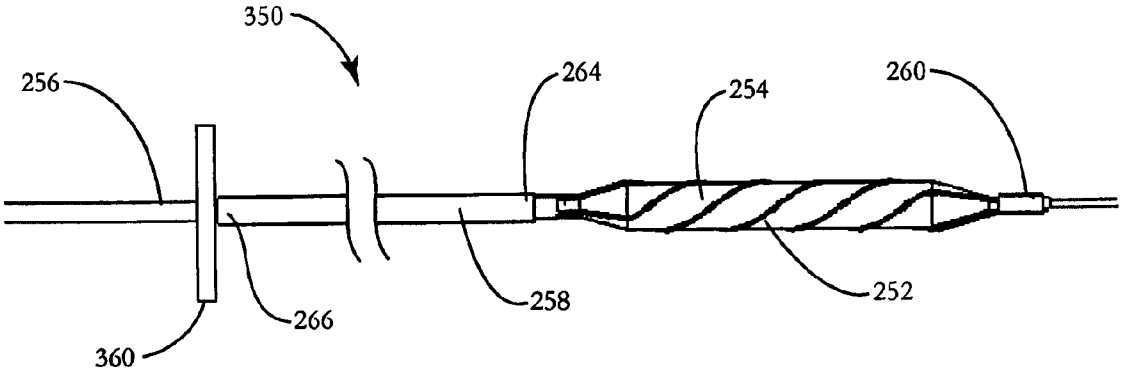
264
254
260
D1
D2
266
258
252

Fig. 19


350
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264
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266
258
252
360

Fig. 20

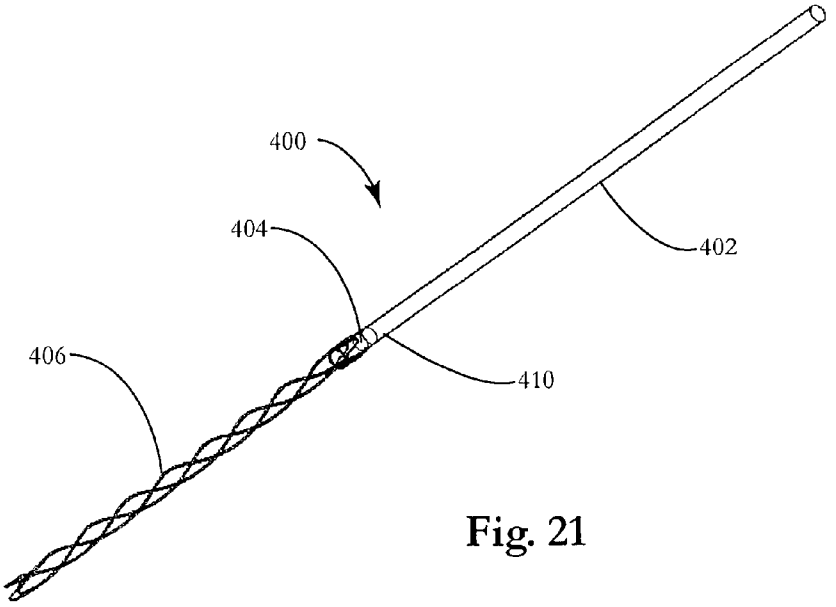

Fig. 21

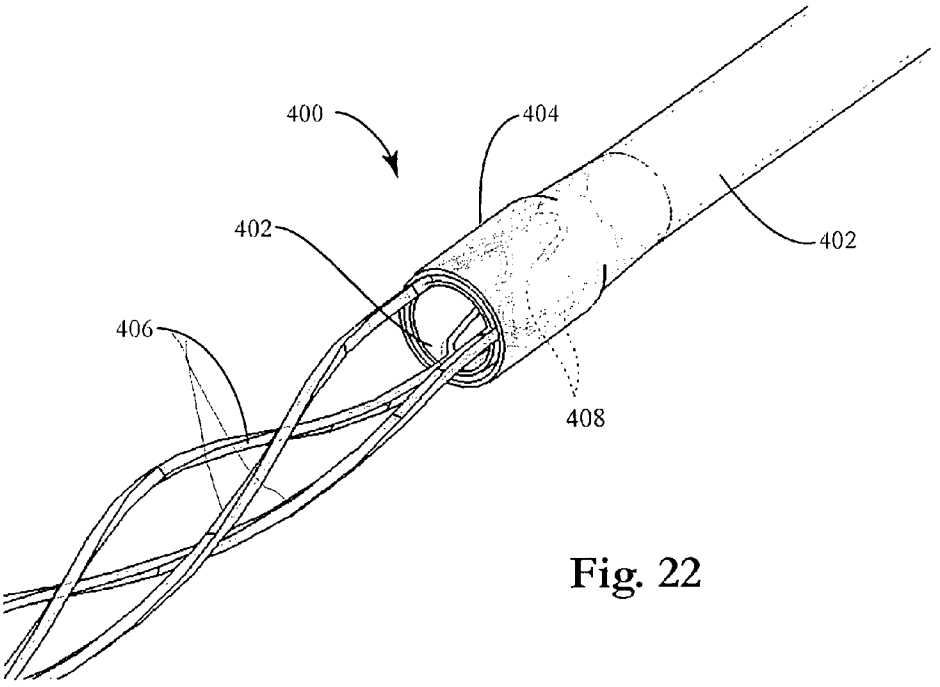

Fig. 22

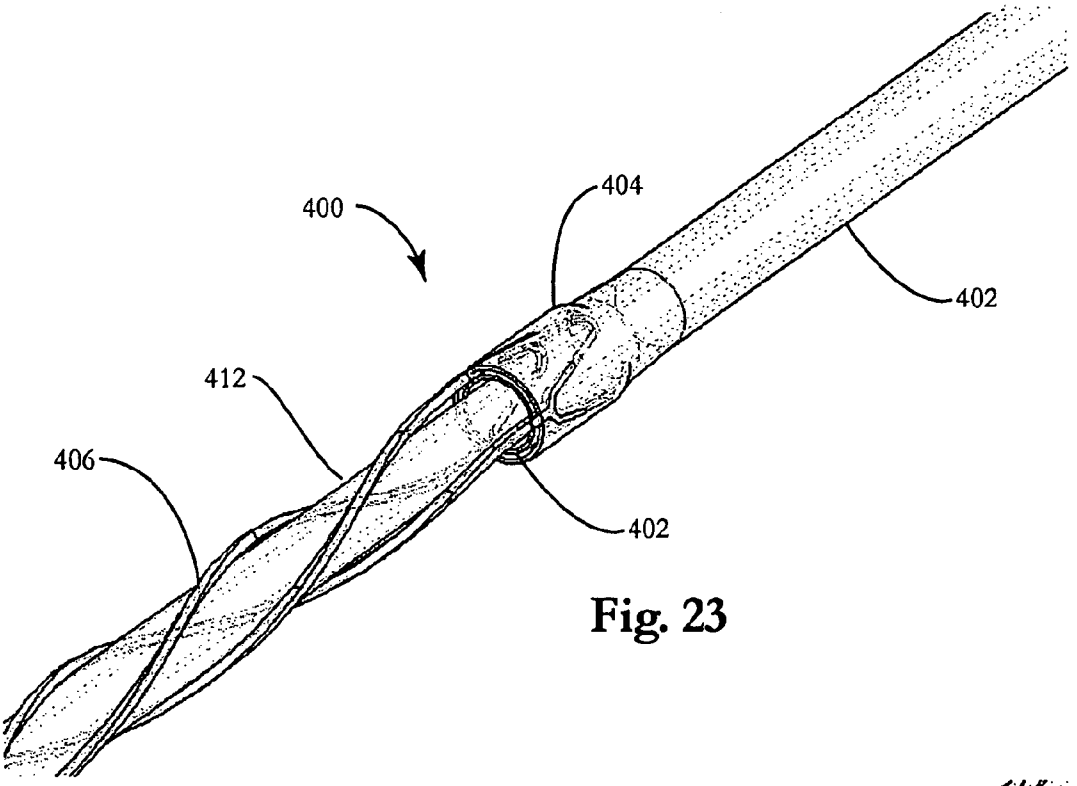

Fig. 23

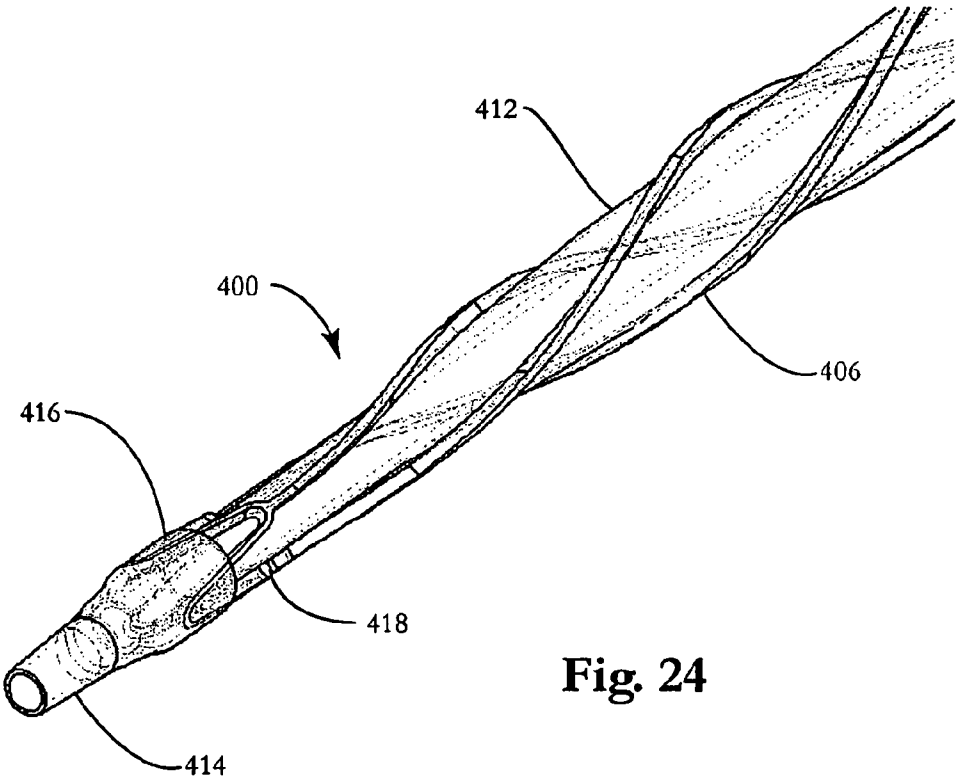

Fig. 24

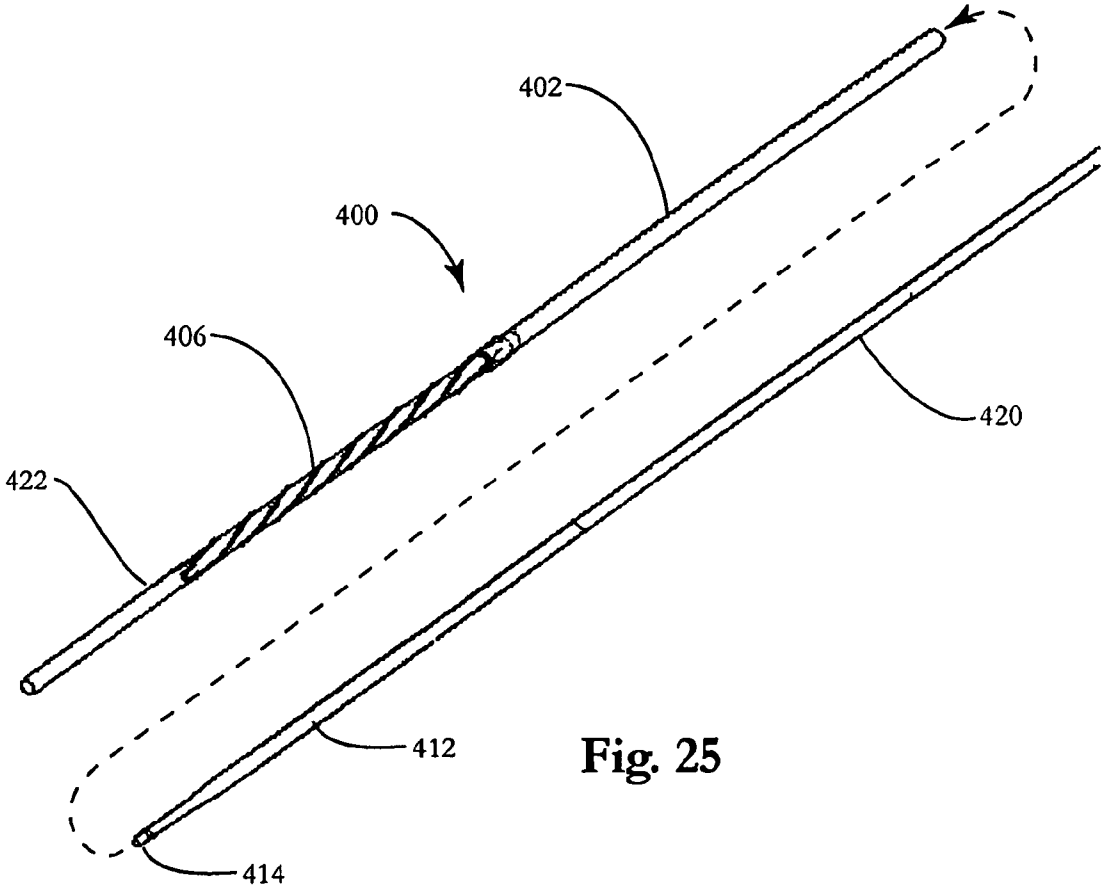

Fig. 25

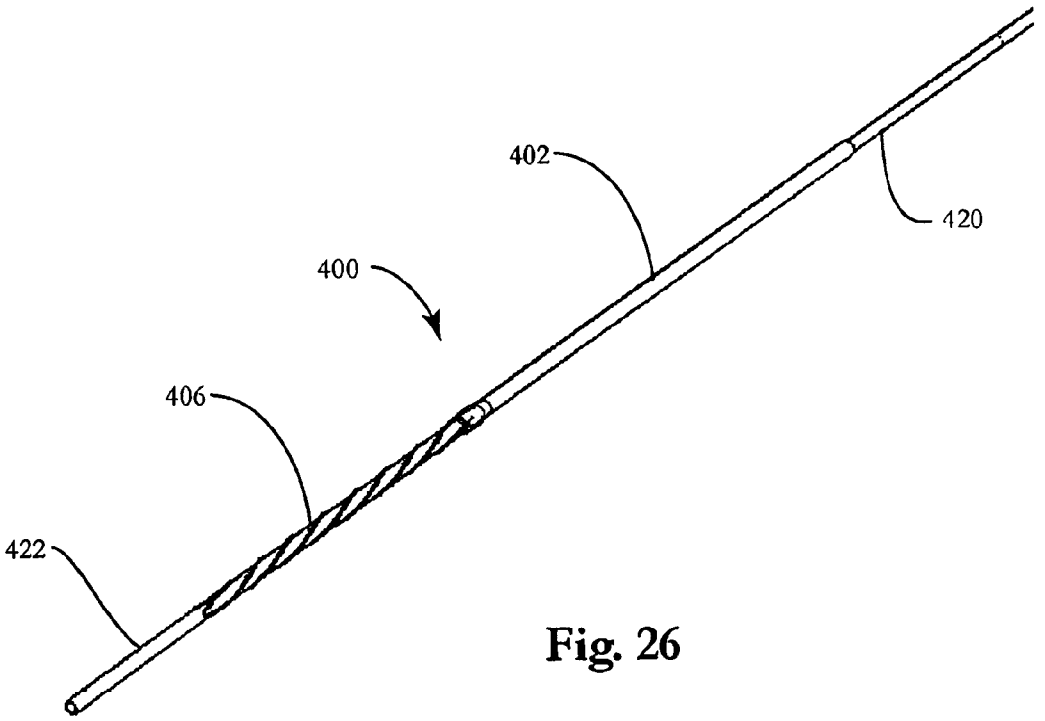

Fig. 26

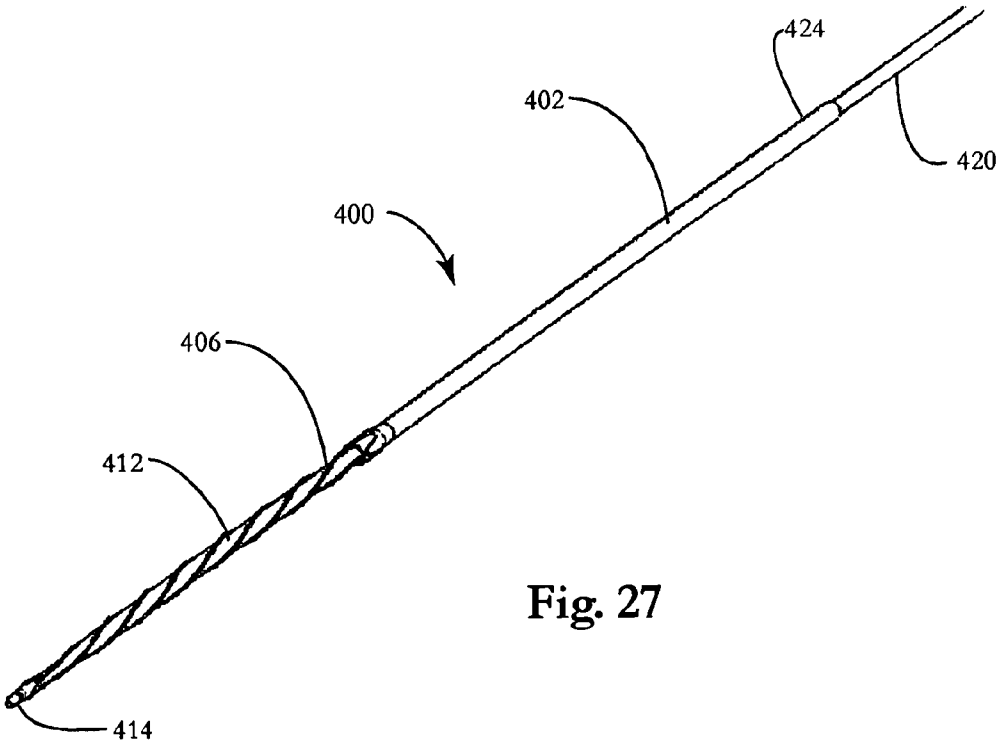

Fig. 27

APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation-in-part of commonly assigned, co-pending U.S. application Ser. No. 10/810,330, filed on Mar. 25, 2004, which is a continuation in part of U.S. application Ser. No. 10/631,499, filed on Jul. 30, 2003, which claims the benefit under 35 USC §119(e) of U.S. Provisional Application No. 60/442,161, filed on Jan. 21, 2003, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the field of medical devices, more specifically medical to devices intended to treat stenoses in the vascular system.

Balloon dilatation (angioplasty) is a common medical procedure mainly directed at revascularization of stenotic vessels by inserting a catheter having a dilatation balloon through the vascular system. The balloon is inflated inside a stenosed region in a blood vessel in order to apply radial pressure to the inner wall of the vessel and widen the stenosed region to enable better blood flow.

In many cases, the balloon dilatation procedure is immediately followed by a stenting procedure where a stent is placed to maintain vessel patency following the angioplasty. Failure of the angioplasty balloon to properly widen the stenotic vessel, however, may result in improper positioning of the stent in the blood vessel. If a drug-eluting stent is used, its effectiveness may be impaired by such improper positioning and the resulting restenosis rate may be higher. This is a result of several factors, including the presence of gaps between the stent and the vessel wall, calcified areas that were not treated properly by the balloon, and others.

Conventional balloon angioplasty suffers from a number of other shortcomings as well. In some cases the balloon dilatation procedure causes damage to the blood vessel due to aggressive balloon inflation that may stretch the diseased vessel beyond its elastic limits. Such over inflation may damage the vessel wall and lead to restenosis of the section that was stretched by the balloon. In other cases, slippage of the balloon during the dilatation procedure may occur. This may result in injury to the vessel wall surrounding the treated lesion. One procedure in which slippage is likely to happen is during treatment of in-stent restenosis, which at present is difficult to treat by angioplasty balloons. Fibrotic lesions are also hard to treat with conventional balloons, and elastic recoil is usually observed after treatment of these lesions. Many long lesions have fibrotic sections that are difficult to treat using angioplasty balloons.

An additional problem associated with balloon angioplasty treatment has been the "watermelon seed effect." Angioplasty is carried out at very high pressures, typically up to twenty atmospheres or higher, and the radially outward pressure of the balloon can cause axial displacement of the balloon in a manner similar to squeezing a watermelon seed with the fingers. Such axial displacement, of course, reduces the effectiveness of balloon dilatation. Another problem with conventional angioplasty balloon design has been deflation of the balloon. Even after the inflation medium is removed from a balloon, the deflated configuration will have a width greater than the original folded configuration which was introduced to the vasculature. Such an increase in profile can make removal of the balloon difficult.

Atherectomy/Thrombectomy devices intended to remove plaque/thrombus material may also include a structure that expands in a lesion while the plaque/thrombus removal mechanism is within this structure. The removed material is either being stacked in the catheter or sucked out thru the catheter. When the procedure is done, the expandable structure is collapsed and the catheter removed. Foreign object removal devices usually include a basket structure that needs to be expanded to collect the object and then collapse for retrieval. Distal protection devices usually include a basket structure that support a mesh that needs to be expanded distal to the treated lesion to collect the loose objects and then collapse for retrieval.

These devices usually include an elastic metallic material that needs to be expanded in the vascular system to fulfill its task and afterwards collapse to a small diameter to facilitate retrieval. The transition between the collapsed (closed) configuration to the expanded (open) configuration can be done in two ways: the structure can be at a normally closed (collapsed) configuration in which force is applied to cause the structure to expand. In this case, the elastic recoil of the structure will cause it to collapse back to closed configuration when the expanding force ceases. The structure may also be at a normally open (expanded) configuration in which a constraining element is forced over it to hold it dawn for the collapsed configuration (for example a constraining tube). When this constraining element is removed the structure is free to expand to the expanded (open) configuration. The structure material may also be non elastic. In this case, the structure will need to be forced to transit between both collapsed and expanded configuration.

One problem associated with conventional angioplasty expansion systems is that the transition between the collapsed and expanded configurations involves significant rotational and axial reaction forces. These reaction forces are applied by the structure on the catheter as a result of the force applied by the catheter to expand or close the structure. Axial reaction forces are created due the foreshortening of the structure during expansion. Rotational reaction forces (torques) are created when a non longitudinal element is forced to expand/collapse. Since the catheters are usually less stiff the structure, these reaction forces may cause that the structure will not expand or collapse properly, or cause undesired deformation to the catheter itself.

To overcome at least some of these problems these problems, U.S. Pat. No. 5,320,634 describes the addition of cutting blades to the balloon. The blades can cut the lesions as the balloon is inflated. U.S. Pat. No. 5,616,149 describes a similar method of attaching sharp cutting edges to the balloon. U.S. Patent Publication 2003/0032973 describes a stent-like structure having non-axial grips for securing an angioplasty balloon during inflation. U.S. Pat. No. 6,129,706 describes a balloon catheter having bumps on its outer surface. U.S. Pat. No. 6,394,995 describes a method of reducing the balloon profile to allow crossing of tight lesions. U.S. Patent Publication 2003/0153870 describes a balloon angioplasty catheter having a flexible elongate elements that create longitudinal channels in a lesion or stenosis.

While the use of angioplasty balloons having cutting blades has proved to be a significant advantage under many circumstances, the present cutting balloon designs and methods for their use continue to suffer from shortcomings. Most commercial cutting balloon designs, including those available from InterVentional Technologies, Inc., of San Diego, Calif., now owned by Boston Scientific, of Natick, Mass.,

have relatively long, axially aligned blades carried on the outer surface of an angioplasty balloon. Typically, the blades are carried on a relatively rigid base directly attached to the outer balloon surface. The addition of such rigid, elongated blade structures makes the balloon itself quite stiff and limits the ability to introduce the balloon through torturous regions of the vasculature, particularly the smaller vessels within the coronary vasculature. Moreover, the cutting balloons can be difficult to deflate and collapse, making removal of the balloons from the vasculature more difficult than with corresponding angioplasty balloons which do not include cutting blades. Additionally, the axially oriented cuts imparted by such conventional cutting balloons do not always provide the improved dilatation and treatment of fibrotic lesions which would be desired.

For these reasons, it would be desirable to provide improved cutting balloon designs and methods for their use. In particular, it would be desirable to provide cutting balloons which are highly flexible over the length of the balloon structure, which readily permit deflation and facilitate removal from the vasculature, and which are effective in treating all forms of vascular stenoses, including but not limited to treatment of highly calcified plaque regions of diseased arteries, treatment of small vessels and/or vessel bifurcations that will not be stented, treatment of ostial lesions, and treatment of in-stent restenosis (ISR). Moreover, it would be desirable if such balloon structures and methods for their use could provide for improved anchoring of the balloon during dilatation of the stenosed region.

It would further be desirable to minimize the reaction forces applied by the external structure to the catheter, and at the same time be able to control the expansion of the expandable structure. It would also be desirable to adjust the compliance of the system in a predictable way without changing the materials or geometry of the expandable structure. At least some of these objectives will be met with the inventions described hereinafter.

2. Description of the Background Art

The following U.S. patents and printed publication relate to cutting balloons and balloon structures: U.S. Pat. Nos. 6,450,988; 6,425,882; 6,394,995; 6,355,013; 6,245,040; 6,210,392; 6,190,356; 6,129,706; 6,123,718; 5,891,090; 5,797,935; 5,779,698; 5,735,816; 5,624,433; 5,616,149; 5,545,132; 5,470,314; 5,320,634; 5,221,261; 5,196,024; and Published U.S. Pat. App. 2003/0032973. Other U.S. patents of interest include U.S. Pat. Nos. 6,454,775; 5,100,423, 4,998,539; 4,969,458; and 4,921,984.

SUMMARY OF THE INVENTION

The present invention provides improved apparatus and methods for the dilatation of stenosed regions in the vasculature. The stenosed regions will often include areas of fibrotic, calcified, or otherwise hardened plaque or other stenotic material of the type which can be difficult to dilatate using conventional angioplasty balloons. The methods and apparatus will often find their greatest use in treatment of the arterial vasculature, including but not limited to the coronary arterial vasculature, but may also find use in treatment of the venous and/or peripheral vasculature, treatment of small vessels and/or vessel bifurcations that will not be stented, treatment of ostial lesions, and treatment of ISR.

In a first aspect of the present invention, a scoring catheter comprises a catheter body having a proximal end and a distal end, a radially expandable shell (typically an angioplasty balloon) near the distal end of the catheter body, and a non-axial scoring structure carried over the shell. By "non-axial scoring structure," it is meant that the structure will be able to score or cut stenotic material within a treated blood vessel along lines which are generally in a non-axial direction. For example, the scoring lines may be helical, serpentine, zig-zag, or may combine some axial components together with such non-axial components. Usually, the non-axial scoring pattern which is imparted will include scoring segments which, when taken in total, circumscribe at least a majority of and usually the entire inside wall of the blood vessel up to one time, preferably more than one time, usually more than two times, often at least three times, more often at least four, five, six, or more times. It is believed that the resulting scoring patterns which circumscribes the inner wall of the vessel will provide improved results during subsequent balloon dilatation.

Usually the scoring structure will comprise at least one continuous, i.e., non-broken, scoring element having a length of at least 0.5 cm, more usually at least 1 cm, often at least 2 cm, usually at least 3 cm, and sometimes at least 4 cm or more. Alternatively, the scoring structure may comprise a plurality of much smaller segments which may be arranged in a helical or other pattern over the balloon, typically having a length in the range from 0.1 cm to 2 cm, often being 0.5 cm or less, sometimes being 0.3 cm or less.

In order to promote scoring of the blood vessel wall when the underlying expandable shell is expanded, the scoring structure will usually have a vessel contact area which is 20% or less of the area of the expandable shell, usually being below 10%, and often being in the range from 1% to 5% of the area of the expandable shell. The use of a shell having such a relatively small contact area increases the amount of force applied to the vascular wall through the structure by expansion of the underlying expandable shell. The scoring structure can have a variety of particular configurations, often being in the form of a wire or slotted tube having a circular, square, or other cross-sectional geometry. Preferably, the components of the scoring structure will comprise a scoring edge, either in the form of a honed blade, a square shoulder, or the like. A presently preferred scoring edge is electropolished and relatively small.

In a preferred embodiment, the scoring structure may be formed as a separate expandable cage which is positioned over the expandable shell of the catheter. The cage will usually have a collar or other attachment structure at each end for placement on the catheter body on either side of the expandable shell. A collar may be a simple tube, and other attachment structures will usually be crimpable or otherwise mechanically attachable to the catheter body, such as a serpentine or other ring structure. The attachment structures on the cage may be attached at both ends to the catheter body, but will more usually be attached at only a single end with the other end being allowed to float freely. Such freedom allows the scoring structure to shorten as the structure is expanded on the expandable shell. In certain embodiments, both ends of the scoring structure will be fixed to the catheter body, but at least one of the attachment structures will have a spring or other compliant attachment component which provides an axial extension as the center of the scoring structure foreshortens.

In many cases, since the scoring elements are non-axial, there are torques induced during the expansion of the balloon and the shortening of the scoring structure. These torques may be high, and if one end of the scoring structure is constrained from rotation, the scoring element will not expand properly. The final expanded configuration of the scoring element is achieved via shortening and rotation.

In a preferred embodiment, both sides of the scoring element are fixed to the catheter, but at least one side will have a compliant structure which will provide axial tension and at the same time will allow the scoring element to rotate to its final configuration.

In some cases both ends of the scoring element are fixed and the shortening is achieved by deformation of the wire. For example, the wire can have a secondary structure which permits elongation (e.g., it may be a coiled filament) or can be formed from a material which permits elongation, e.g., nitinol. The scoring element can be attached in both ends, in a way that will allow rotation. In the case were the torques are low (depending on the design of the scoring element) there is no need for rotation and the torque can be absorbed either be the scoring element of by the catheter.

In all cases, the scoring structure is preferably composed of an elastic material, more preferably a super elastic material, such as nitinol. The scoring structure is thus elastically expanded over the expandable shell, typically an inflatable balloon similar to a conventional angioplasty balloon. Upon deflation, the scoring structure will elastically close to its original non-expanded configuration, thus helping to close and contain the balloon or other expandable shell.

In some cases the scoring element will be a combination of more than one material. In one case the scoring element can be made from nitinol and parts of it can be made from stainless steel. In other cases the scoring element can be made of stainless steel or nitinol and part of it can be made from polymer to allow high deformations.

In other preferred embodiments, the assembly of the shell and the scoring structure will be sufficiently flexible to permit passage through tortuous regions of the vasculature, e.g., being capable of bending at radius of 10 mm or below when advanced through 45°, 90° or higher bends in the coronary vasculature. Usually, the scoring structure will comprise one or more scoring elements, wherein less than 70% of the cumulative length of the scoring element is aligned axially on the shell when expanded, preferably being less than 50% of the cumulative length, and more preferably being less than 25% of the cumulative length. In other instances, the scoring structure may comprise one or more scoring elements, wherein the cumulative length of the scoring element includes a non-axial component of at least 10 mm, preferably at least 12 mm, and more preferably 36 mm. Preferably, at least some of the scoring elements will have scoring edges which are oriented radially outwardly along at least a major portion of their lengths at all times during inflation and deflation and while inflated. By "radially outward," it is meant that a sharp edge or shoulder of the element will be oriented to score or cut into the stenotic material or the interior wall of the treated vessel, particularly as the shell is being inflated.

The scoring elements will usually, but not necessarily, have a scoring edge formed over at least a portion of their lengths. A "scoring edge" may comprise a sharpened or honed region, like a knife blade, or a square shoulder as in scissors or other shearing elements. Alternatively, the scoring elements may be free from defined scoring edges, e.g., having circular or the other non-cutting profiles. Such circular scoring elements will concentrate the radially outward force of the balloon to cause scoring or other disruption of the plaque or other stenotic material being treated.

In a second aspect of the present invention, the scoring catheter comprises a catheter body and a radially expandable shell, generally as set forth above. The scoring structure will be composed of elements which circumscribe the radially expandable shell. By "circumscribing the radially expandable shell," it is meant that at least some scoring elements of the scoring structure will form a continuous peripheral path about the exterior of the expandable shell during expansion. An example of such a fully circumscribing structure is a helical structure which completes up to one 360° path about the balloon before, during and after expansion, usually completing two complete revolutions, and frequently completing three, four, or more complete revolutions. Exemplary helical structures may include two, three, four, or more separate elements, each of which is helically arranged around the radially expandable shell.

In a third aspect of the present invention, a scoring catheter comprises a catheter body and a radially expandable shell, generally as set forth above. An elongated scoring structure is carried over the shell, and the assembly of the shell and the scoring structure will be highly flexible to facilitate introduction over a guide wire, preferably being sufficiently flexible when unexpanded so that it can be bent at an angle of at least 90°, preferably 180°, at a radius of 1 cm without kinking or otherwise being damaged. Such flexibility can be determined, for example, by providing a solid cylinder having a radius of 1 cm and conforming the assembly of the scoring structure and expandable shell over the cylinder. Alternatively, the assembly can be advanced over a guide wire or similar element having a 180° one centimeter radius bend. In either case, if assembly bends without kinking or other damage, it meets the requirement described above. Other specific features in this further embodiment of the catheters of the present invention are as described above in connection with the prior embodiments.

In a fourth aspect of the present invention, a plaque scoring catheter comprises a catheter body and a radially expandable balloon, generally as set forth above. A plurality of scoring elements are distributed over the balloon, typically being attached directly to an outer surface of the balloon. The scoring elements will be relatively short, typically having lengths below about 25% of the balloon length, preferably having lengths in the range from 2% to 10% of the balloon length. The relatively short, segmented scoring elements will permit highly flexible assemblies of balloon and scoring elements, generally meeting the flexibility requirement set forth above. The scoring elements may be arranged randomly over the balloon but will more usually be distributed uniformly over the balloon. In specific embodiments, the scoring elements may be arranged in helical, serpentine, or other regular patterns which circumscribe the balloon. As the balloon expands, such short segments will generally move apart from each other, but will still impart the desired scoring patterns into the vascular wall as the balloon is inflated.

In a fifth embodiment, the scoring catheter according to the present invention comprises a catheter body and a radially expandable balloon generally as set forth above. The balloon has a plurality of lobes extending between ends of the balloons, and at least one scoring element will be formed on at least one of the lobes in a manner arranged to score stenotic material as the balloon is expanded. The lobe will usually be in a helical pattern, and typically two, three, or more lobes will be provided. In the case of helical lobes, the scoring element(s) will usually be disposed along a helical peak defined by the helical lobe when the balloon is inflated. Such helical scoring elements will be arranged to accommodate balloon inflation, typically being stretchable, segmented, or the like.

In still another aspect of the apparatus of the present invention, an expandable scoring cage is adapted to be carried over a balloon of a balloon catheter. The scoring cage comprises an assembly of one or more elongate elastic scoring elements arranged in a non-axial pattern. As defined above, the non-

axial pattern may comprise both axial and non-axial segments. The assembly is normally in a radially collapsed configuration and is expandable over a balloon to a radially expanded configuration. After the balloon is deflated, the assembly returns to a radially collapsed configuration, preferably being assisted by the elastic nature of the scoring cage. Advantageously, the scoring cage will enhance uniform expansion of the underlying balloon or other expandable shell and will inhibit "dog boning" where an angioplasty balloon tends to over inflate at each end, increasing the risk of vessel dissection. The scoring elements will be adapted to score hardened stenotic material, such as plaque or fibrotic material, when expanded by the balloon in a blood vessel lumen. The scoring cage may be adapted to mount over the balloon with either or both ends affixed to the balloon, generally as described above in connection with prior embodiments. Preferred geometries for the scoring elements include those which circumscribe the balloon, those which are arranged helically over the balloon, those which are arranged in a serpentine pattern over balloon and the like.

In yet another aspect of the present invention, a method for dilatating a stenosed region in a blood vessel comprises radially expanding a shell which carries a scoring structure. The scoring structure scores and dilates the stenosed region and includes one or more non-axial scoring elements arranged to impart a circumscribing score pattern about the inner wall of the blood vessel as the shell is expanded. The stenosed region is typically characterized by the presence of calcified plaque, fibrotic plaque, or other hardened stenotic material which is preferably scored prior to dilatation. Preferably, the scoring structure will not be moved in axial direction while engaged against the stenosed region, and the scoring structure may optionally be free from axially scoring elements.

In still another aspect of the present invention, an angioplasty catheter comprises a catheter body and a radially expandable shell near the distal end of the catheter body. An external structure, such as a scoring structure or cutting structure, is carried over but unattached to the shell. The catheter further comprises an attachment structure having a proximal end and a distal end attached to the scoring structure, wherein the attachment structure is sufficiently sized and compliant to accommodate reaction forces or geometrical changes produced by the scoring structure as it is expanded by the shell. Generally, at least a portion of said scoring structure is arranged helically over the shell. However, the scoring structure may comprise numerous different configurations as described above.

In one aspect of the present invention, the proximal end of the attachment structure is fixed to the catheter body and the distal end of the attachment structure is secured to the proximal end of the scoring structure. In all cases, the attachment structure is capable axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In a preferred embodiment, the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body. The inner diameter of the compliance tube is generally larger than an outer diameter of the catheter body so that the compliance tube freely extends and/or rotates with respect to the catheter body as the scoring structure foreshortens.

The compliance tube may also be sized to control the compliance of the scoring structure and expandable shell. Generally, the compliance tube has wall thickness ranging from 0.001 in to 0.1 in., preferably 0.005 in. to 0.05 in. The wall thickness may be increased to lessen the compliance of the system, or decreased to create a greater compliance. The length of the compliance tube may also be adjusted to control the compliance of the system. Generally, compliance tube has a length ranging from 1 cm to 10 cm, but may range up to 30 cm or more for embodiments wherein the tube extends across the length of the catheter body.

In most cases, the material of the compliance tube may also be selected to control the compliance of the scoring structure and expandable shell. Generally, the compliance tube comprises an elastic material, preferably a polymer such as nylon or Pebax™. Alternatively, the compliance tube may comprise a braided material, metal or wire mesh.

In some aspects of the present invention, the compliance tube may have one or more perforations to control the compliance of the scoring structure and expandable shell. Generally, the perforations comprise one or more slots extending along the outside circumference of the compliance tube. The slots may form a pattern along the outside circumference of the compliance tube. The slots may be parallel to each other, and/or extend helically or radially across the circumference of the compliance tube. The slots themselves may be formed of a variety of shapes, such as circular or rectangular.

Preferably, compliance tube has an outer diameter that tapers from its distal end to its proximal end so that the outside diameter at the proximal end is slightly larger than the inner diameter, and the outside diameter at the distal end is sized to approximate the diameter of the scoring structure when in a collapsed configuration. This allows for the catheter to be readily removed from a vessel without catching or snagging on the vessel wall. For the tapered configuration, the outer diameter of the compliance tube will vary depending on the size of the catheter body and the expansion cage, but the diameter generally tapers down in the range of 0.004 in to 0.010 in. from the distal end to the proximal end.

In another aspect of the invention, the attachment structure is connected at its distal end to the scoring structure and at its proximal end to a manipulator. Typically, the manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the scoring structure across the length of the catheter body. In all cases, the attachment structure is capable of axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In a preferred embodiment, the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body. Typically, the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely extends and rotates with respect to the catheter body as the scoring structure foreshortens. The compliance of the scoring structure and expandable shell may be controlled by adjusting the thickness, length, or material selection of the compliance tube.

In some embodiments, the compliance of the scoring structure is controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. Specifically, the attachment structure may be axially advanced with respect to the catheter body as the balloon is being inflated or deflated. For example, the attachment structure may be pulled away from the distal end of the catheter body while the balloon is being expanded to constrain the compliance of balloon. Alternatively, the manipulator may be used to rotate the attachment structure with respect to the catheter body to control the compliance of the balloon during transition.

In another embodiment of the present invention, a method of dilatating a stenosed region in a blood vessel comprises introducing a scoring structure carried over an expandable shell that is connected to a catheter body by an attachment

structure, and expanding the scoring structure within a stenosed region within the blood vessel. In this method, the attachment structure axially and/or rotationally extends to accommodate foreshortening of the scoring structure as the shell is expanded. The attachment structure generally comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body, wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely extends and rotates with respect to the catheter body as the scoring structure foreshortens. The thickness, length, and material of the compliance tube may be selected to control the compliance of the scoring structure and expandable shell.

In some embodiments, the method further comprises the step of fixing the proximal end of the attachment structure to the catheter body. Alternatively, the method may comprise the step of fixing the proximal end of the attachment structure to a manipulator. In such an embodiment, manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the scoring structure across the length of the catheter body. This allows for the compliance of the scoring structure and balloon to be controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. Actuation of the manipulator may occur by axially advancing, pulling or rotating the attachment structure with respect to the catheter body.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**, **1**A, **1**B and **1**C are schematic illustrations of the balloon scoring structure embodiment in accordance with an embodiment of the invention.

FIG. **2** is a schematic illustration of an exemplary helical scoring structure embodiment in accordance with embodiments of the invention.

FIG. **3** is a schematic illustration of an expanded angioplasty balloon carrying a helical scoring structure in accordance with embodiments of the invention.

FIG. **4** illustrates a scoring structure comprising an alternating serpentine pattern of intermediate scoring elements between a pair of end collars.

FIG. **5** illustrates the serpentine scoring elements of the embodiment of FIG. **4** showed in a rolled-out configuration.

FIG. **6** illustrates a scoring structure comprising alternating C-shaped scoring elements between a pair of end collars.

FIG. **7** illustrates the C-shaped scoring elements of the embodiment of FIG. **6** shown in a rolled-out configuration.

FIG. **8** is a view of one of the C-shaped scoring elements taken along line **8**-**8** of FIG. **6**.

FIG. **9** illustrates an alternative double C-shaped scoring element which could be utilized on a scoring structure similar to that illustrated in FIG. **6**.

FIG. **10** illustrates an alternative embodiment of a helical scoring structure comprising serpentine and zigzag structures for mounting onto a balloon catheter.

FIG. **11** illustrates a first of the serpentine mounting elements of the scoring structure of FIG. **10**.

FIG. **12** illustrates a second of the serpentine mounting elements of the scoring structure of FIG. **10**.

FIG. **13** illustrates an alternative mounting structure for a helical or other scoring structure.

FIG. **14** illustrates the mounting structure of FIG. **13** shown in a rolled-out configuration.

FIG. **15** shows yet another embodiment of a mounting element for the scoring structures of the present invention.

FIG. **16** illustrates the mounting structure of FIG. **15** shown in a rolled-out configuration.

FIG. **17***a* illustrates yet another alternative embodiment of a catheter constructed in accordance with the principles of the present invention, where an attachment structure is disposed between the scoring structure and the catheter body.

FIG. **17***b* illustrates the structure of FIG. **17***a* shown without the balloon.

FIGS. **18***a-c* illustrate a catheter constructed in accordance with the principles of the present invention having an attachment structure with various patterned perforations.

FIG. **19** illustrates another embodiment of a catheter constructed in accordance with the principles of the present invention having a tapered attachment structure.

FIG. **20** illustrates yet another alternative embodiment of a catheter constructed in accordance with the principles of the present invention, where an attachment structure is connected to a manipulator.

FIG. **21** illustrates an embodiment of the invention having a laminated section at the distal end of the compliance tube.

FIG. **22** illustrates another view of the embodiment of FIG. **21**.

FIG. **23** illustrates the embodiment of FIG. **21** with an expandable balloon inserted within the scoring structure.

FIG. **24** illustrates an embodiment with a sleeve over the distal end of the scoring structure.

FIG. **25** illustrates a method of the present invention utilizing an insertion tube to mount the scoring structure over the expandable balloon.

FIG. **26** illustrates shows the insertion tube inserted over the expandable balloon.

FIG. **27** illustrates a scoring catheter of the present invention with the insertion tube removed.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well-known features may be omitted or simplified in order not to obscure the present invention.

Embodiments of the present invention relate to device for revascularization of stenotic vessels and specifically to a balloon catheter having external elements. The dilatation device comprises a conventional dilatation balloon such as a polymeric balloon and a spiral, or external elements with other configurations mounted on the balloon catheter.

Reference is now made to FIGS. **1**, **1**A and **1**B, which are schematic illustrations of a dilatation device **10** in accordance with embodiments of the invention. The dilatation device **10** includes a dilatation balloon **12**, which may be any conventional angioplasty balloon such as commonly used by interventional cardiologists or radiologists, and a helical or spiral unit **14** mounted over or attached to dilatation balloon **12**. The compliance of the balloon and the scoring element(s) should be chosen to assure uniform expansion of the balloon substantially free from "dog-boning" as the combined structure expands within a lesion. If a compliant or a semi-compliant balloon is used and the compliance of the scoring element was not matched to comply with the properties of the balloon, the expansion of the balloon-scoring element system will not be uniform. This non-uniformity may impair the efficacy of the scoring catheter and, in some cases, may result in poor per-

formance. For example, under given pressure, certain parts of the balloon will be able to expand while other parts will be constrained by excessive resistance of the scoring elements.

Helical unit **14** typically made of nitinol. Helical unit **14** may be made of other metals such stainless steel, cobalt-chromium alloy, titanium, and the like. Alternatively, spiral unit **14** may be a polymeric spiral, or made of another elastic material. Helical unit **14** may be attached at its proximal and distal ends to the proximal end **17** and distal end **18** of dilatation balloon **12**. Alternatively, spiral unit **14** may be attached to the distal end and/or the proximal end of dilatation balloon **12** by collar-like attachment elements **15** and **16**. Spring or other compliant elements may be alternatively or additionally provided as part of the attachment elements to accommodate shortening of the helical unit as it is expanded.

Dilatation device **10** is inserted into the vascular system, for example, using a conventional catheter procedure, to a region of stenotic material **22** of blood vessel **20**. (The term "stenotic" is used herein to refer to the vascular lesion, e.g., the narrowed portion of the vessel that the balloon is meant to open.) At the stenotic area, the dilatation balloon **12** is inflated, for example, by liquid flow into the balloon. Helical unit **14** widens on the inflated dilatation balloon **12**. On inflation, the dilatation balloon **12** together with the helical unit **14** is pressed against the walls of blood vessel **20** as shown in FIG. **1**B.

Reference is now made to FIG. **1**C, illustrating blood vessel **20** after the deflation of dilatation balloon **12**. Helical unit **14** narrows when deflating the dilatation balloon **12**, thus the dilatation device **10** is narrowed and may be readily retrieved from blood vessel **20**. The deflation profile of the balloon **10** is low and mainly circular. The stenotic material **22** in blood vessel **20** is pressed against blood vessel **20** walls to widen the available lumen and enhance blood flow. The pressing of helical unit **14** against the walls of blood vessel **20** causes scoring **23** in the stenotic area.

Reference is now made to FIG. **3** that shows a scoring structure in the form of a single wire **24** wrapped around a dilatation balloon **12** in a helical configuration.

In other embodiments, the scoring structure of the present invention can have a non-helical configuration. Any design of scoring structure that can accommodate an increase in the diameter of the balloon **12** upon inflation, and return to its configuration when the balloon is deflated, is an appropriate design useful in the invention. At least a portion of the scoring elements will not be parallel to the longitudinal axis of the balloon catheter to enhance flexibility and improve scoring.

Referring again to FIGS. **1**A-**1**C, helical unit **14** is pushed outwardly by the inflation of the balloon **12**, and is stretched by the inflation of the balloon. When the balloon is deflated, helical unit **14** assists in the deflation by its elastic recoil. This active deflation is faster and also leads to a low profile of the deflated balloon. The balloon **12** is disposed within the helical unit **14**, which returns to its pre-inflated shape and forces the balloon to gain a low radial profile.

In another embodiment of the invention, dilatation device **10** may carry a stent. The stent can be crimped over the helical unit **14**. In this way, the helical unit **14** can push the stent against hard areas of the lesion, enabling proper positioning of the stent against the vessel wall, even in hard-calcified lesions without pre-dilation.

Reference is now made to FIG. **2**, illustrating the helical unit **14** in accordance with embodiments of the invention. Helical unit **14** is typically made of nitinol. Helical unit **14** includes three wires **19** that are attached to collars **15** and **16** at the proximal end and distal end, respectively. Alternatively the scoring structure may be formed as a metallic cage, which can be made from a slotted tube, or polymeric cage or polymeric external elements. Alternatively the scoring structure may comprise wires of other elements attached directly to the balloon material or close to the balloon ends.

Wires **19** (FIG. **2**) are attached between collars **14** and **15**. The diameter of the wires is typically in the range of 0.05 mm to 0.5 mm. Alternatively, a cage (for example a metallic cage made of a slotted tube) can be used in several configurations that allow local stress concentrations. The size and shape of the cross section of the cage elements or the cross section of the wires can vary. The cross section can be a circle, rectangle, triangle, or other shape.

In alternative embodiments, the wires **19** may comprise short segments that are attached to the balloon **12**.

In further alternative embodiments of the invention, the helical unit **14** may be glued, thermally bonded, fused or mechanically attached at one or both ends to dilatation balloon **12**.

In yet another embodiment, a scoring structure may comprise wires that are attached to the dilatation balloon **12** in helical configuration or other configuration. The wires may be thermally attached to the balloon **12**, glued, mechanically attached, or the like.

In still another embodiment, a scoring structure comprises wire or cage elements that are not parallel to the longitudinal axis of the balloon **12** so that the combination of the scoring structure **19** and the balloon **12** remains flexible.

In additional embodiments, the combination of dilatation balloon **12** and scoring structure scores the lesion and provides better vessel preparation for drug eluting stents by allowing better positioning of the stent against the vessel wall and diffusion of the drug through the scores in the lesion.

In these embodiments, the balloon can be used as a platform to carry drugs to the lesion where scoring of the lesion can enhance delivery of the drug to the vessel wall.

In these embodiments, the balloon can be used for a local drug delivery by embedding drug capsules, drug containing polymer, and the like, through the stenotic material and into the vessel wall.

From the above, it can be seen that the invention comprises catheters and scoring structures, where the scoring structures are positioned over the balloons or other expandable shells of the catheter. The scoring structures may be attached directly to the balloons or other shells, in some cases being embedded in the balloon material, but will more usually be formed as separate cage structures which are positioned over the balloon and attached to the catheter through attachment elements on either side of the balloon. The expandable cages may be formed using conventional medical device fabrication techniques, such as those used for fabricating stents, such as laser cutting of hypotube and other tubular structures, EDM forming of hypotubes and tubes, welding of wires and other components and the like.

Typically, such expandable shell structures will comprise the attachment elements and an intermediate scoring section between the attachment elements. As illustrated in the embodiments above, the attachment elements may be simple cylindrical or tube structures which circumscribe the catheter body on either side of the balloon or other expandable shell. The simple tube structures may float over the catheter body, i.e., be unattached, or may be fixed to the catheter body. A number of alternative embodiments for the attachment elements will be described in connections with the embodiments below.

The intermediate scoring sections may also have a variety of configurations where at least some of the scoring elements will typically be disposed in a non-axial configuration, i.e., in

a direction which is not parallel to the axial direction of the expandable cage. A preferred configuration for the intermediate scoring section comprises one or more helical elements, generally as illustrated in the prior embodiments. Other exemplary configurations are set forth in the embodiments described below.

Referring now in particular to FIGS. **4** and **5**, an expandable scoring cage **100** comprises first and second attachment elements **102** and **104**, respectively, and an intermediate scoring section **106** comprising a plurality of curved serpentine members **110**. The serpentine members **110** extend circumferentially in opposite directions in an alternating manner. This can be understood by observing a "rolled-out" view of the serpentine elements as illustrated in FIG. **5**. A second alternative scoring cage structure **120** is illustrated in FIGS. **6-8**. The scoring cage **120** comprises first and second attachment elements **122** and **124** joined by a spine **126**. Plurality of C-shaped scoring elements **128** and **130** are attached to the spine and extend in opposite circumferential directions. The shape of the element can be observed in FIG. **8**. The opposite directions may be observed in the rolled-out view of FIG. **7**.

It will be appreciated that a variety of different circumferential structures may be used in place of the C-shaped structures of FIGS. **6-8**. For example, a pair of opposed C-shaped partial ring structures may be utilized, as illustrated in FIG. **9**. The C-shaped structures of FIG. **6** or the double C-shaped structures of FIG. **9** can also be extended so that they wrap around a balloon more than one time, either over or under the spine structure **126**.

The expandable cage structures **100** and **120** will each be mounted over a dilatation balloon, such as the balloon of FIGS. **1-3**, with the attachment elements secured to the catheter body on either side of the dilatation balloon. The tube or cylindrical attachment elements **102**, **104**, **122**, and **124** may simply float over the catheter body. In other embodiments, however, it may be desirable to use an adhesive or other means for affixing either one or both of the attachment elements to the catheter body. Having at least one floating attachment element, however, is often desirable since it can accommodate shortening of the intermediate scoring section as that section radially expands. In other cases, however, the individual scoring elements may possess sufficient elasticity to accommodate such shortening. For example, nitinol and other shape memory alloys possess significant stretchability, typically on the order of 8% which in some instances will be sufficient to accommodate any tension applied on the intermediate scoring section by radial expansion of the balloon.

Referring now to FIGS. **10-12**, alternative attachment elements are shown on an embodiment of an expandable scoring cage **140** comprising three helical scoring elements **142** which make up the intermediate scoring section. A first attachment element **146** comprises a single serpentine ring, as best illustrated in FIG. **11** while a second attachment element **148** comprises a pair of tandem serpentine rings **150** and **152**, as best illustrated in FIG. **12**. The use of such serpentine attachment structures is beneficial since it permits crimping of either or both of the structures onto the catheter body in order to fix either or both ends of the structure thereto. Usually, the single serpentine attachment structure **48** will be affixed to the catheter body while the double serpentine structure will be left free to allow movement of that end of the scoring cage to accommodate radial expansion of the underlying balloon.

Referring now to FIGS. **13** and **14**, a further alternative embodiment of an attachment element useful in the scoring cages of the present invention is illustrated. Attachment element **180** includes a pair of serpentine rings **182** and **184**, generally as shown in FIG. **12**, in combination with a coil spring structure **186** located between said rings **182** and **184**. The coil spring structure **186** includes three nested coil springs **190**, each joining one of the bend structures **192** and **194** on the serpentine rings **182** and **184**, respectively. The structure of the spring structure and adjacent serpentine rings can be understood with reference to the rolled-out configuration shown in FIG. **14**.

The attachment structure **180** is advantageous since it permits a fixed attachment of the outermost ring **182** to the underlying catheter body while the inner ring **184** remains floating and expansion and contraction of the intermediate scoring section, comprising helical elements **196**, is accommodated by the coil spring structure **186**. Since the scoring cage is fixed to the catheter, any risk of loss or slippage from the balloon is reduced while sufficient compliance is provided to easily accommodate radial expansion of the intermediate scoring section. By attaching the structures **180** at at least one, and preferably both ends of the scoring cage, the risk of interference with a stent is reduced.

In some embodiments, collars, such as those shown in FIGS. **1** and **2**, or attachment elements, such as those shown in FIGS. **10-12**, may comprise a flexible material that allows the collar or attachment element to expand while being mounted over the balloon catheter and then be collapsed to the diameter of the catheter. The expandability of the collars and/or attachment elements may be achieved by a compliant memory material such as nitinol or a polymer, or by use of a flexible serpentine design as shown in FIGS. **10-12**. Where collars are used, the collar may be shaped or have a slit down the circumference (not shown) so that the collar may be expanded during mounting over the balloon. Alternatively, the collar may be oversized to accommodate the balloon diameter mounting, and then crimped down to secure the secure the scoring structure to the catheter body.

Yet another embodiment of the attachment element of the present invention includes an axial spring as shown in FIGS. **15** and **16**. The attachment element **200** includes a terminal serpentine ring **202** and an intermediate spring structure **204** including a number of axial serpentine spring elements **206**. The nature of the serpentine ring elements **206** can be observed in the rolled-out configuration of FIG. **16**. Optionally, a second serpentine ring **210** may be provided between the attachment structure **200** and the helical scoring elements of the intermediate scoring section **212**.

The embodiments of FIGS. **13-16** comprise spring-like elements **186** and **204** to accommodate axial shortening of the scoring structure upon radial expansion. It will be appreciated that other metal and non-metal axially extensible structures could also be used in such attachment structures. For example, elastic polymeric tubes could be attached at one end to the scoring structures and at another end to the catheter body (or to a ring, collar or other structure which in turn is fixed to the catheter body).

Referring now to FIGS. **17***a* and **17***b*, a further embodiment of an angioplasty catheter **250** having an axially distensible attachment structure **258** is illustrated. External structure **252** is held over expandable dilatation balloon **254** and is fixed at one end to the distal end **260** of catheter body **256**. The external structure may comprise any structure typically used for removal of plaque/thrombus from a vessel wall such as a scoring structure, cutting structure or crushing structure. The proximal end **262** of external structure **252** is connected to the distal end **264** of attachment structure **258**. The proximal end **266** of attachment structure **258** is fixed to the catheter body **256**. As described below, the attachment structure **258** may be

configured to reduce forces applied on the external structure **252** and the catheter body **256** during expansion and contraction of balloon **254**.

In a preferred embodiment, attachment structure **258** comprises a cylindrical over-tube, or compliance tube, made of an elastic material. Over-tube **258** generally has an inner diameter that is slightly greater than the outer diameter of the catheter body **256**. Because only a small section of the proximal end of the attachment structure **258** is fixed to the catheter body, the distal end **264** attached to external structure **252** is free floating, and is free to slide axially and rotationally with respect to catheter body **256**. Attachment structure **252** may be fixed, for example by adhesion, directly to the to catheter body **256** and external structure **252**, or to a collar or other intermediate attachment means.

As balloon **254** is expanded, external structure **252** expands in circumference and contracts axially along the catheter body **256**, creating axial force A on attachment structure **258**. Attachment structure **258**, fixed to the catheter at its end **266**, axially stretches to accommodate the axial movement of the external structure **252**. External structure **252** also tends to rotate about the catheter body **256**, causing a torsional force T. The distal end **264** of attachment structure **258** rotates through the full range of motion of scoring structure **252** to accommodate torsional force T, while proximal end **266** remains stationary with respect to catheter body **256**.

The configuration illustrated in FIGS. **17***a* and **17***b* allows the compliance of the expandable system to be controlled. Generally, where one end of the scoring structure is free, the compliance of the expandable system will be a combination of the compliance of the balloon and the scoring structure. However, because the ends of the expandable system shown in FIG. **17** are fixed at distal end **260** and proximal end **266**, the attachment structure controls the compliance of the expandable system.

The compliance of the system may be varied by any combination of material selection, wall thickness, or length of the over-tube **258**. Over-tube **258** may comprise any elastomer, such as elastic polymer like Nylon, Pebax, or PET. Typically, compliance tube **258** is formed from extruded tubing, but is may also comprise braided polymeric or metallic fibers, or wire mesh. A high memory metal such as nitinol or stainless steel may also be used. Where the compliance tube comprises an extruded polymeric tube, the wall thickness can vary in the ranges set forth above, and the length of the tube can range from 1 cm to 10 cm. For the same material, the thinner-walled and longer the tube, the more compliant the system.

Referring to FIGS. **18***a-c*, the compliance of a angioplasty catheter **300** may also be varied by creating one or more perforations in compliance tube **258**. The perforations may comprise one or more slots in the circumference of the tubing. The slots may comprise one continuous slot spiraling across the length of compliance tube **258**, or may be a number of slots aligned in any number of patterns, such as helical **312**, or radial **314**. The slots may also be any number of shapes, such as circular or rectangular, and may have a discreet length or be contiguous across the surface of the compliance tube.

Referring to FIG. **19**, the outside diameter of compliance tube **258** may be tapered to facilitate delivery and retrieval of the scoring catheter **320** from the treatment site within the lumen. Generally, the outer diameter will be larger at the distal end **264** of the compliance tube **258** and smaller at the proximal end **266** of the compliance tube. The outside diameter D_1 at the distal end will vary depending on the profile of the scoring structure and balloon when collapsed but typically range from 0.004 in. to 0.01 in. larger than the outside diameter D_2 at the proximal end. The outside diameter D_2 at the proximal end is generally as close as possible to the outside diameter of the catheter body to create a smooth transition between the compliance tube and the catheter. As an example, for a catheter body having an outside diameter of 0.033 in., outside diameter D_1 at the distal end may be 0.042 in. with an inner diameter of 0.038 in., the inner diameter providing clearance between the catheter body so that the distal end of the compliance tube can move relative to the catheter body. Correspondingly, the outside diameter D_2 at the proximal end may taper down to 0.0345 in., with an inner diameter of 0.034 in. to closely match the catheter body having outside diameter with enough clearance to be bonded to the catheter body by an adhesive.

The taper may run across the whole length of the compliance tube, or alternatively be only tapered at a section of the length of the compliance tube. The tapered compliance tube **258** smoothes the transition between the scoring structure and catheter body, and minimizes the likelihood of the outer tube or scoring structure snagging or catching on a portion of the luminal wall during delivery or retrieval of the catheter.

Now referring to FIG. **20**, an alternative embodiment of a scoring catheter **350** is shown having a manipulator **360**. The attachment structure **258** is connected at its distal end **264** to the scoring structure **252**. Instead of being secured directly to the catheter body **256**, the proximal end **266** is attached to manipulator **360**. Typically, the manipulator **360** is positioned at the proximal end of the catheter body **256** and the attachment structure **258** extends from the scoring structure across the length of the catheter body. Like the above embodiments, the attachment structure is capable of axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In some embodiments, the compliance of the scoring structure **252** and balloon **254** is controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. In one aspect, the attachment structure **258** may be axially advanced with respect to the catheter body **256** as the balloon is being inflated or deflated. For example, the attachment structure **258** may be pulled away from the distal end of the catheter body **256** while the balloon **254** is being expanded to constrain the compliance of balloon. The attachment structure **258** may also be pulled away from the distal end of the catheter body **256** during or after the balloon **254** is being deflated to minimize the profile of the balloon and scoring structure. Alternatively, the manipulator **360** may be used to rotate the attachment structure **258** with respect to the catheter body **256** to control the compliance of the balloon and scoring structure during transition from a collapsed to expanded state and back to a collapsed state.

Now referring to FIGS. **21** and **22**, a scoring cage structure **400** is illustrated having a two-layer laminated compliance tube **402**. As shown in FIG. **22**, the compliance tube **402** has a laminated structure **404** at at least its distal end **410**. The laminated structure holds the proximal ends **408** of the scoring elements **406** as shown in broken line in FIG. **22**. The scoring elements **406** may be sized to fit over the outside of the compliance tube **402**, as illustrated in FIG. **22**, with the lamination covering the elements. Alternatively, the compliance sleeve tube **402** may be sized to fit inside of the scoring structure **406**, with the laminating layer(s) formed over the elements **406** (not shown).

The laminating structure may be composed of a polymer similar to the compliance tube **402**, and may be heat shrunk or melted to thermally bond the compliance sleeve to the compliance tube and sandwich the scoring structure **406**. Alternatively, an adhesive or other bonding method such as ultrasonic or RF energy may be used to laminate the structure. The

laminated structure as shown in FIGS. **21** and **22**, provides a smoothed transition and strengthened bond between the scoring cage and the attachment structure. Such a smooth transition is a particular advantage when withdrawing the scoring cage from the vasculature.

FIGS. **23** and **24** illustrate scoring cage **400** positioned over an expandable dilation balloon **412**. As shown in FIG. **24**, distal end **418**, of the scoring structure may be coupled to the distal tip **414** of the catheter body by an end cap **416**. The end cap **416** may be composed of a compatible polymer and thermally bonded with the catheter body to fix distal end **418** of the scoring structure to the catheter body.

Now referring to FIGS. **25-27**, a method is illustrated for mounting an expandable scoring cage **406** over a balloon catheter. The scoring cage **406** is pre-expanded by loading it over an insertion tube **422** that has an inner diameter slightly larger than the outer diameter of the balloon **412**. A catheter body **420** having a balloon **412** is then inserted into the inner diameter of the insertion tube **422** and advanced until the balloon **412** is appropriately positioned with respect to the scoring structure **406**, as illustrated in FIG. **26**. The insertion tube **422** is then pulled back to allow the expanded scoring structure to collapse over the balloon **412** and the catheter body **420**, as shown in FIG. **27**. The scoring structure **406** may then be secured at its distal end **418** to the distal tip **414** of the catheter body **420** and the proximal end **424** of the scoring structure/attachment structure assembly to a medial location on the catheter body **420**.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Alternate embodiments are contemplated that fall within the scope of the invention.

What is claimed is:

1. An angioplasty catheter comprising:

a catheter body having a proximal end and a distal end;

a radially expandable shell near the distal end of the catheter body;

an external structure carried over but unattached to the shell, wherein the external structure has a distal end fixedly attached to the catheter body at a location distal to the radially expansible shell so that a proximal end of the external structure is drawn distally axially and/or rotates relative to the catheter body as the shell is radially expanded; and

an attachment structure having a proximal end fixedly attached to the catheter body and a distal end attached to the proximal end of the external structure, wherein the attachment structure is sufficiently sized and compliant to accommodate movements of the external structure relative to the catheter body which are produced by the external structure as it is expanded by the shell wherein the attachment structure comprises an elastic polymeric compliance tube having an outer diameter and an inner diameter that extends over the catheter body, wherein the distal end of the compliance tube does not extend over the radially expansible shell.

2. A catheter as in claim **1**, wherein the external structure comprises a scoring structure.

3. A catheter as in claim **1**, wherein the external structure comprises a cutting structure.

4. A catheter as in claim **1**, wherein at least a portion of the external structure is arranged helically over the shell.

5. A catheter as in claim **1**, wherein the attachment structure twists to accommodate rotation of the external structure as the shell is expanded.

6. A catheter as in claim **1**, wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube can narrow as it lengthens with respect to the catheter body as the external structure foreshortens.

7. A catheter as in claim **1**, wherein the compliance tube is composed of a polymer is selected from the group consisting of nylon and Pebax.

8. A catheter as in claim **7**, wherein the compliance tube has a wall thickness ranging from 0.001 in. to 0.1 in.

9. A catheter as in claim **8**, wherein the compliance tube has a length ranging from 1 cm to 10 cm.

10. A catheter as in claim **1**, wherein a distal end of the compliance tube is laminated over a proximal end of the external structure.

11. A catheter as in claim **10**, wherein a sleeve is laminated to the compliance tube using a thermal bond.

12. A catheter as in claim **10**, wherein a sleeve is laminated to the compliance tube with an adhesive.

13. A catheter as in claim **10**, wherein the end of the external structure is fixed to a distal end of the catheter body.

14. A catheter as in claim **1**, wherein the compliance tube has one or more perforations.

15. A catheter as in claim **14**, wherein the one or more perforations comprise one or more slots extending along the outside circumference of the compliance tube.

16. A catheter as in claim **15**, wherein the slots form a pattern along the outside circumference of the compliance tube.

17. A catheter as in claim **16**, wherein the slots are parallel to each other.

18. A catheter as in claim **16**, wherein the slots extend helically across the compliance tube.

19. A catheter as in claim **16**, wherein the slots extend radially across the compliance tube.

20. A catheter as in claim **16**, wherein the slots are circular in shape.

21. A catheter as in claim **16**, wherein the slots are rectangular in shape.

22. A catheter as in claim **1**, wherein the compliance tube has an outer diameter that tapers from its distal end to its proximal end.

23. A catheter as in claim **22**, wherein the outer diameter of the compliance tube tapers down from in the range of 0.004 in. to 0.010 in. from the distal end and to the proximal end.

24. A catheter as in claim **1**, wherein the attachment structure is connected at its proximal end to a manipulator.

25. A catheter as in claim **24**, wherein the manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the external structure across the length of the catheter body.

26. A catheter as in claim **24**, wherein the attachment structure axially extends to accommodate foreshortening of the external structure as the shell is expanded.

27. A catheter as in claim **26**, wherein the attachment structure twists to accommodate rotation of the external structure as the shell is expanded.

28. A catheter as in claim **27**, wherein the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body.

29. A catheter as in claim **28**, wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance can lengthen and twist with respect to the catheter body as the external structure foreshortens.

30. A catheter as in claim **29**, wherein the compliance of the external structure is controlled by actuating the manipulator during expansion of the radially expandable shell.

31. A catheter as in any of claim 30, wherein actuating the manipulator comprises axially advancing the attachment structure with respect to the catheter body.

32. A catheter as in claim 31, wherein axially advancing the attachment structure comprises pulling the attachment structure away from the distal end of the catheter body.

33. A catheter as in any of claim 30, wherein actuating the manipulator comprises rotating the attachment structure with respect to the catheter body.

34. A catheter as in claim 29, wherein the compliance of the external structure is controlled by actuating the manipulator during contraction of the radially expandable shell.

35. A method of dilating a stenosed region in a blood vessel, the method comprising:

introducing an external structure having a distal end and a proximal end carried over an expandable shell, wherein the external structure is unattached to the shell, the distal end is fixedly attached to a catheter body, and the proximal end is connected to the catheter body by an attachment structure; and

expanding the expandable shell to dilate external structure within the stenosed region within the blood vessel, wherein the proximal end of the external structure moves distally and the attachment structure axially lengthens to accommodate such distal movement of the external structure as the shell is expanded, wherein the attachment structure comprises a compliance tube having an outer diameter and an inner diameter, wherein the compliance tube extends over the catheter body.

36. A method as in claim 35, wherein the attachment structure further accommodates rotation of the external structure as the shell is expanded.

37. A method as in claim 36, wherein the external structure has a proximal end and a distal end, and wherein the proximal end of the attachment structure is fixed to the catheter body.

38. A method as in claim 36, wherein the external structure has a proximal end and a distal end, and wherein the method further comprises the step of fixing the proximal end of the attachment structure to a manipulator.

39. A method as in claim 38, wherein the manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the external structure across the length of the catheter body.

40. A method as in claim 39, wherein the compliance of the external structure is controlled by actuating the manipulator during expansion of the radially expandable shell.

41. A method as in any of claim 40, wherein actuating the manipulator comprises axially advancing attachment structure with respect to the catheter body.

42. A method as in claim 41, wherein axially advancing attachment structure comprises pulling the attachment structure away from the distal end of the catheter body.

43. A method as in any of claim 40, wherein actuating the manipulator comprises rotating the attachment structure with respect to the catheter body.

44. A method as in claim 39, wherein the compliance of the external structure is controlled by actuating the manipulator during contraction of the radially expandable shell.

45. A method as in claim 35, wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely lengthens and rotates with respect to the catheter body as the external structure foreshortens.

46. A method as in claim 45, wherein the compliance tube has a wall thickness ranging from 0.001 in. to 0.1 in.

47. A method as in claim 46, wherein the compliance tube has a length ranging from 1 cm to 10 cm.

48. A method as in claim 35, wherein the compliance tube comprises an elastic material.

49. A method as in claim 48, wherein the compliance tube comprises a polymer.

* * * * *

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(12) **United States Patent**
Konstantino et al.

(10) **Patent No.: US 8,454,636 B2**
(45) **Date of Patent: *Jun. 4, 2013**

(54) **APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS**

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(73) Assignee: **AngioScore, Inc.**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/292,716**

(22) Filed: **Nov. 9, 2011**

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Related U.S. Application Data

(63) Continuation of application No. 10/917,917, filed on Aug. 13, 2004, now Pat. No. 8,080,026, which is a continuation-in-part of application No. 10/810,330, filed on Mar. 25, 2004, now Pat. No. 7,955,350, which is a continuation-in-part of application No. 10/631,499, filed on Jul. 30, 2003, now Pat. No. 7,686,824.

(60) Provisional application No. 60/442,161, filed on Jan. 21, 2003.

(51) **Int. Cl.**
A61B 17/22 (2006.01)

(52) **U.S. Cl.**
USPC **606/159**; 623/1.11

(58) **Field of Classification Search**
USPC 606/159, 194; 604/22, 500; 623/1.11
See application file for complete search history.

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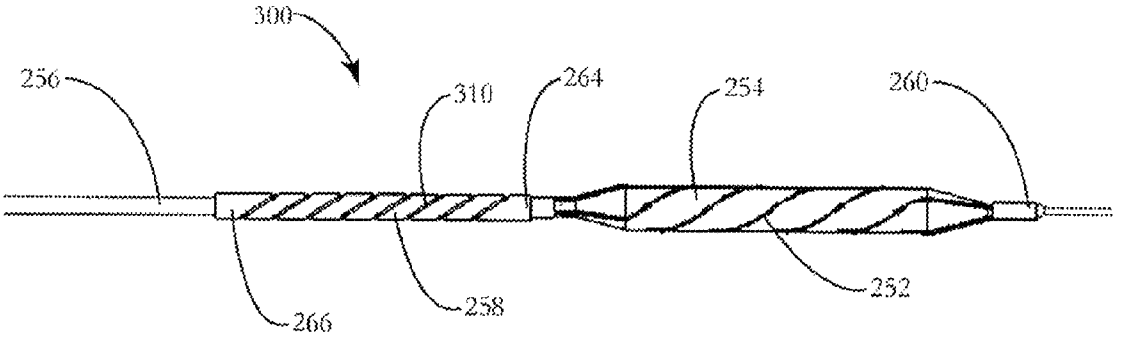
Primary Examiner — Victor Nguyen
(74) *Attorney, Agent, or Firm* — Sheppard Mullin Richter & Hampton LLP

(57) **ABSTRACT**

An angioplasty catheter includes a catheter body having a balloon or other radially expandable shell at its distal end. A non-axial external structure is carried over the shell and scores a stenosed region in a blood vessel when the balloon is inflated therein. The catheter has an attachment structure disposed between the catheter body and the balloon to accommodate foreshortening and rotation of the external structure as the balloon is expanded. The external structure may be part of a helical cage structure which floats over the balloon.

19 Claims, 15 Drawing Sheets



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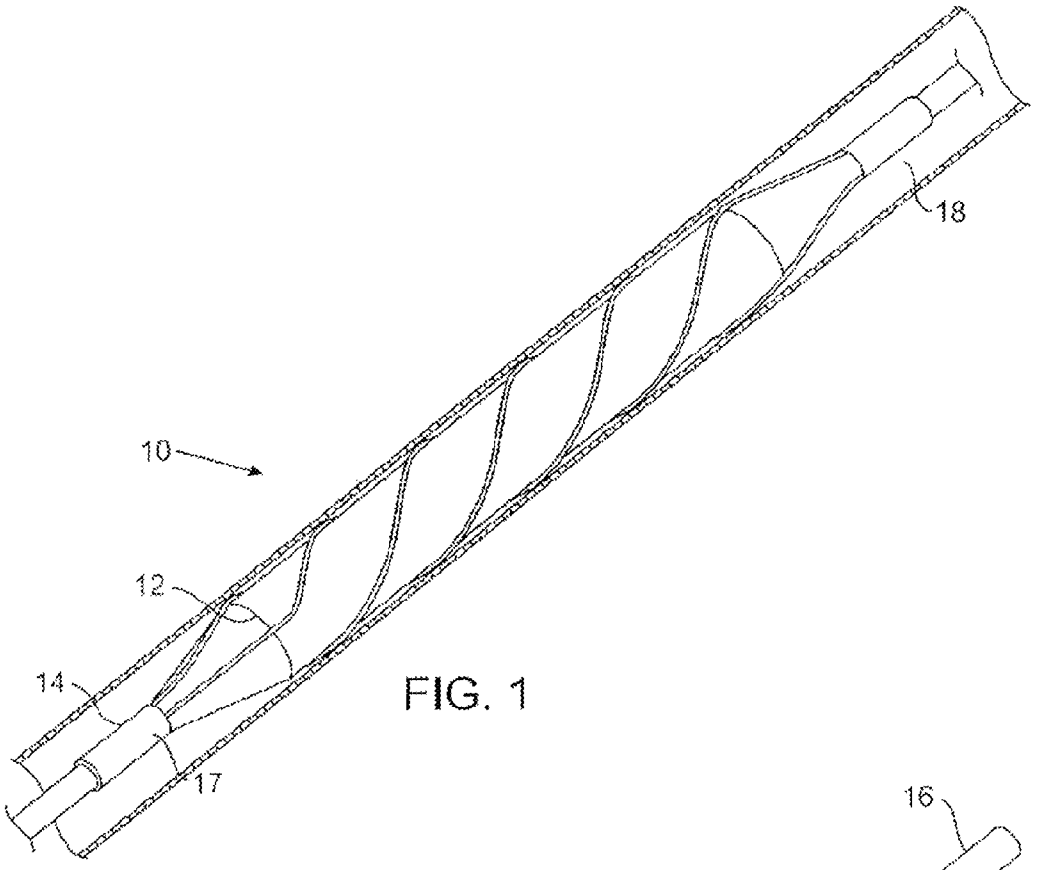


FIG. 1

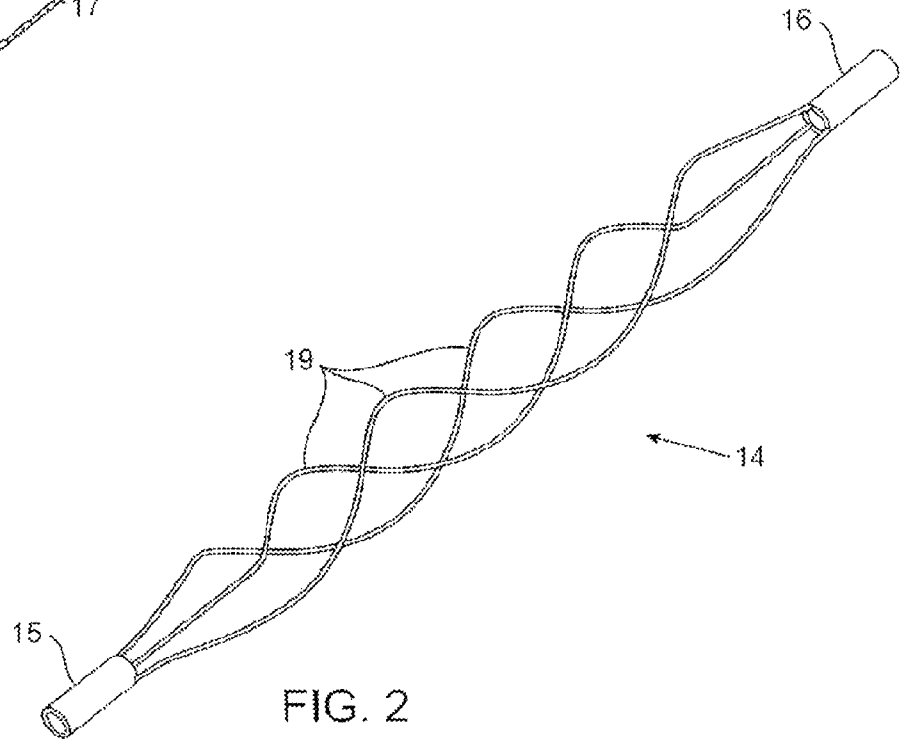
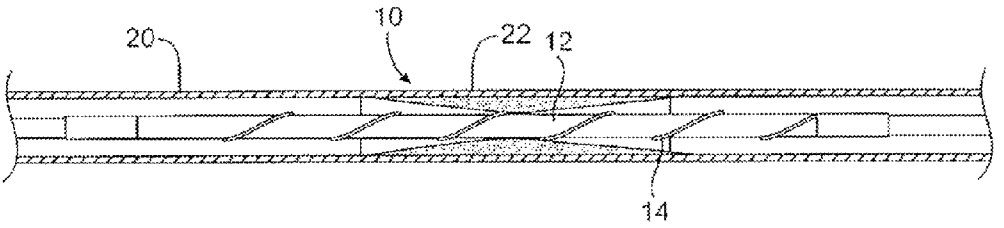


FIG. 2



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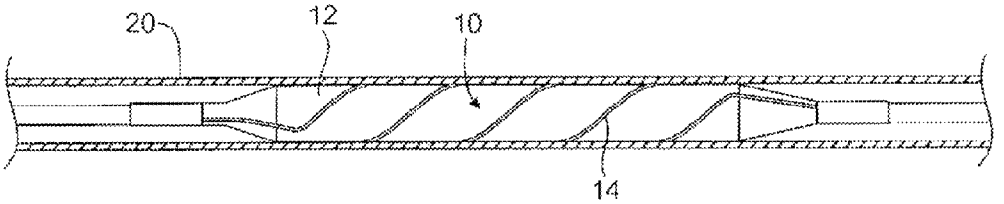

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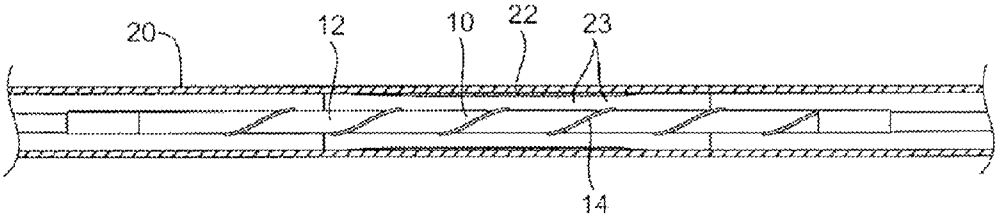
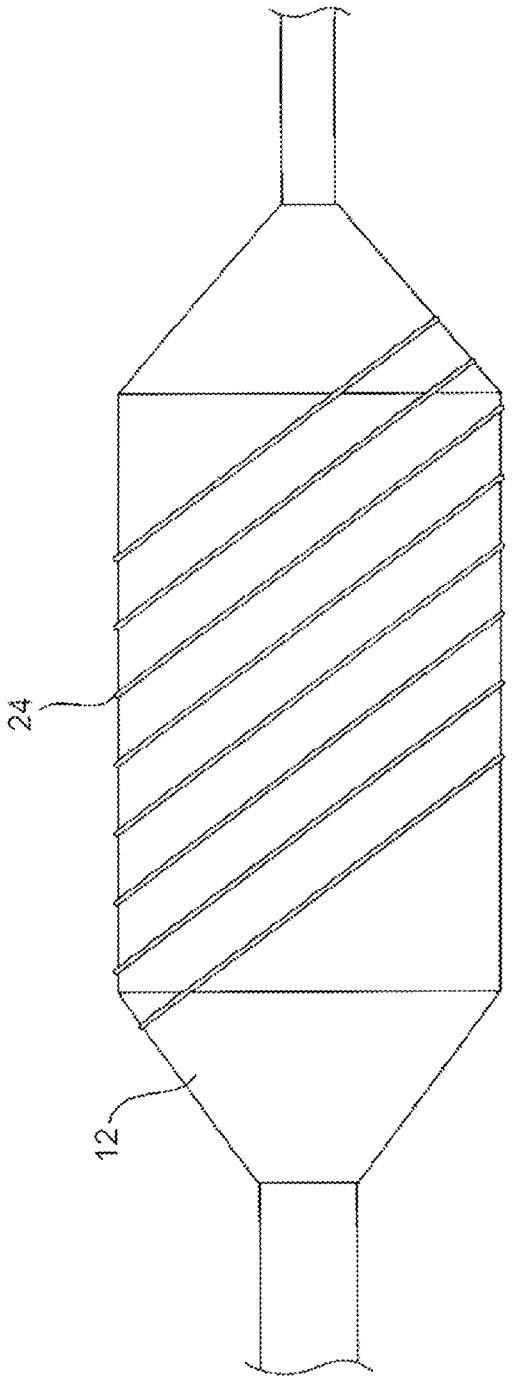


FIG. 1C



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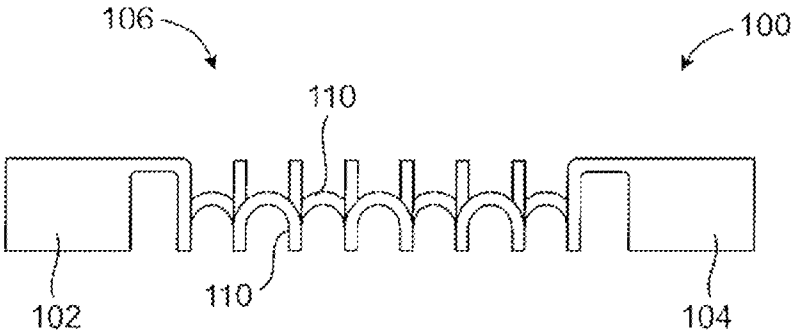


FIG. 4

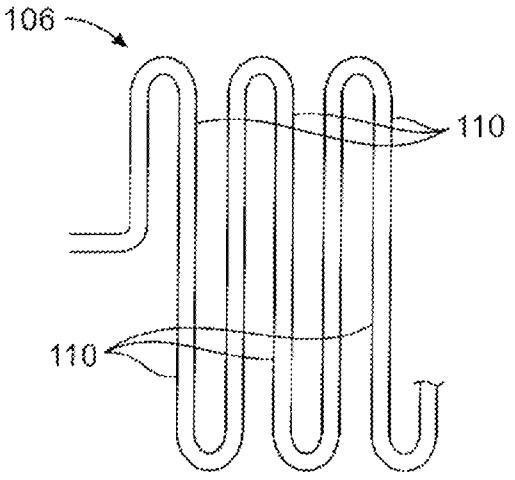


FIG. 5

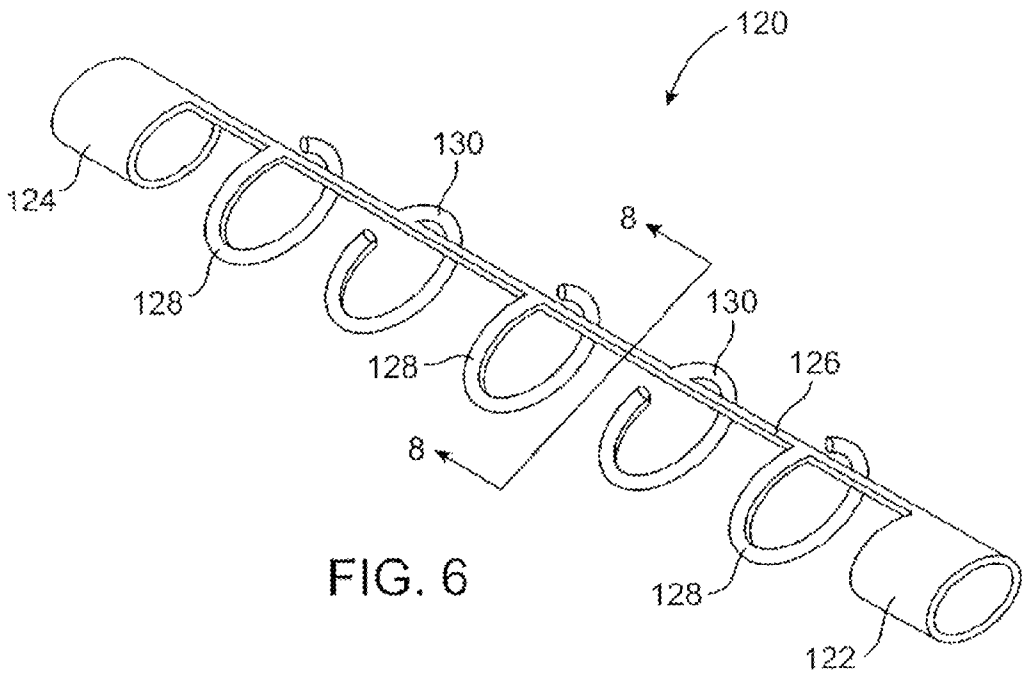


FIG. 6

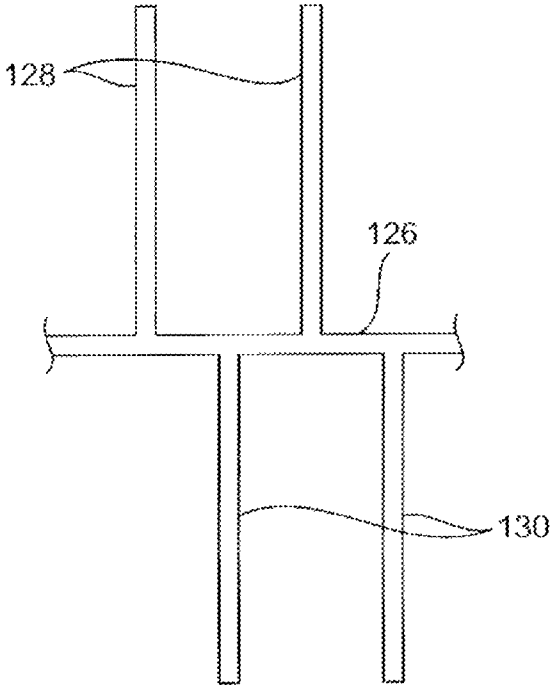


FIG. 7

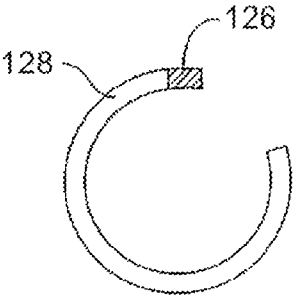


FIG. 8

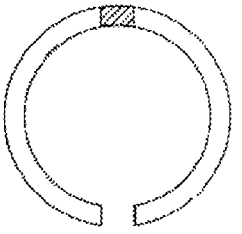


FIG. 9

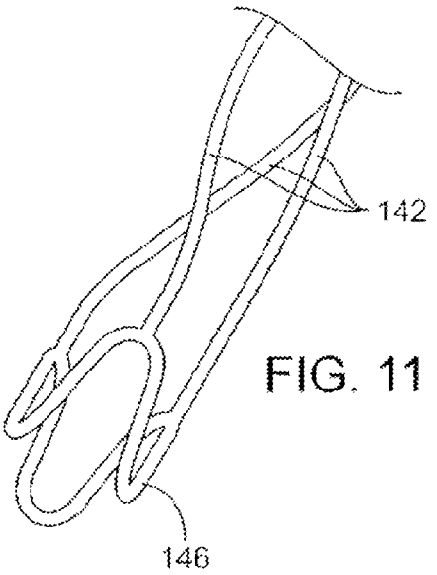


FIG. 11

FIG. 10

FIG. 12

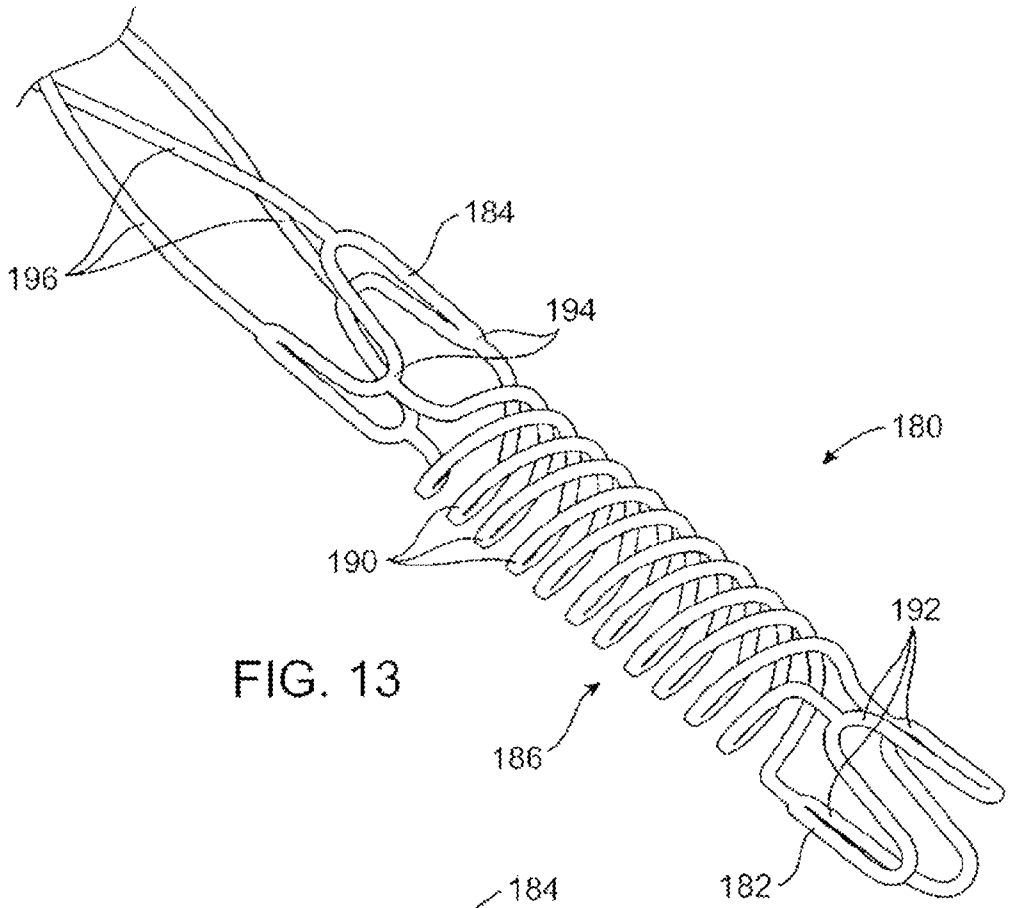


FIG. 13

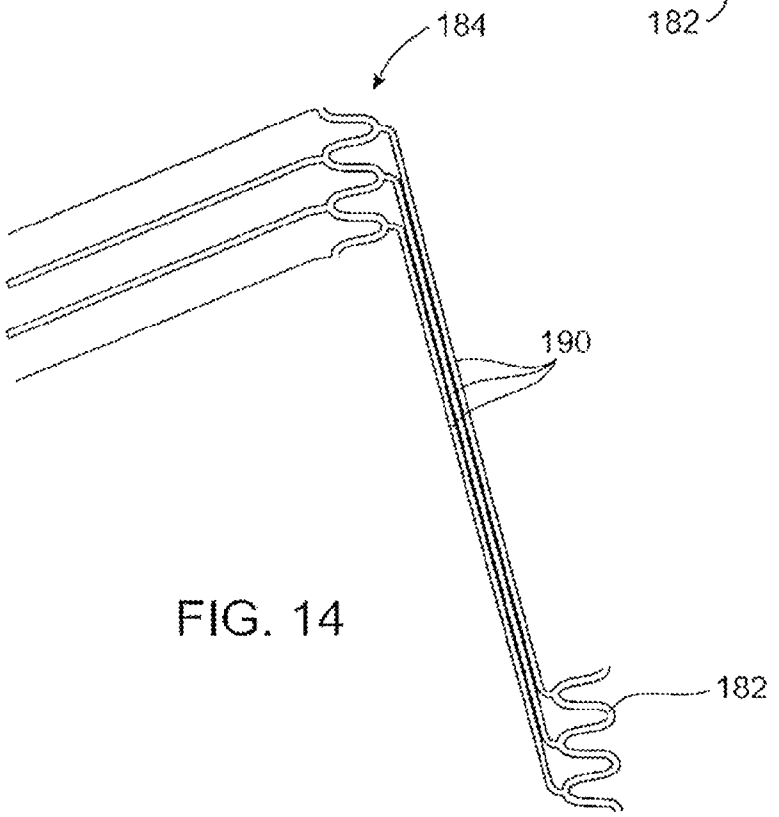


FIG. 14

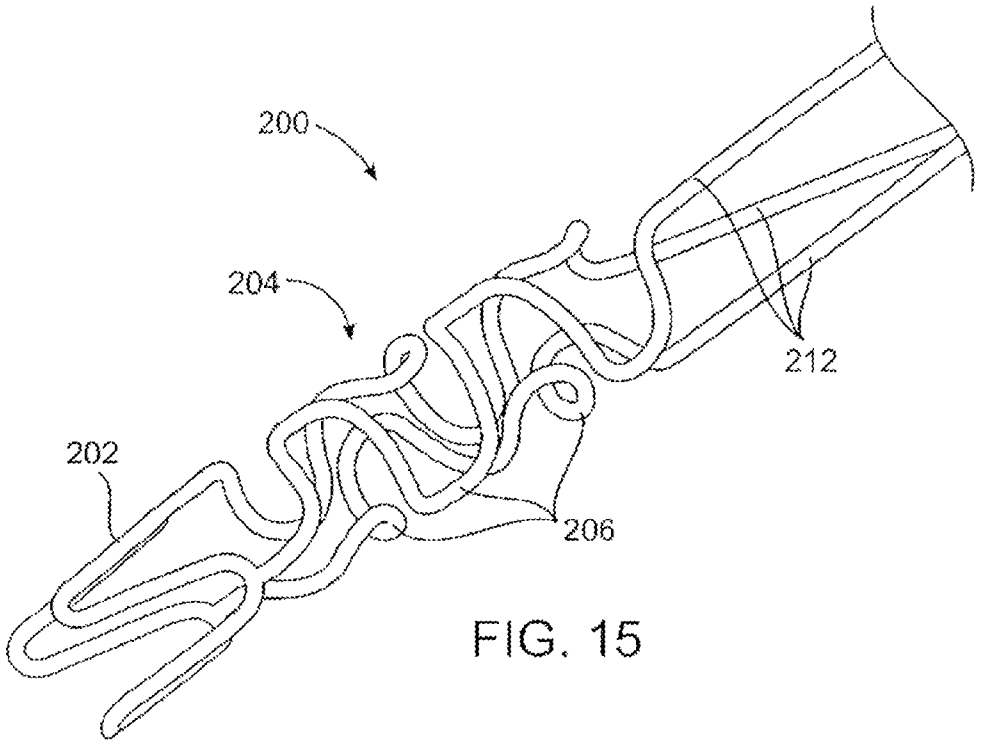


FIG. 15

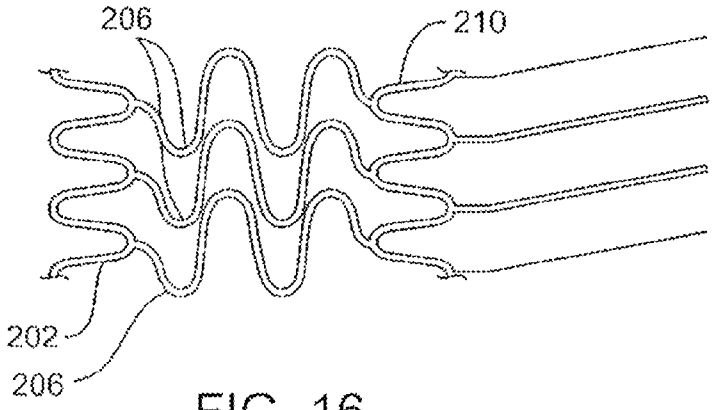


FIG. 16

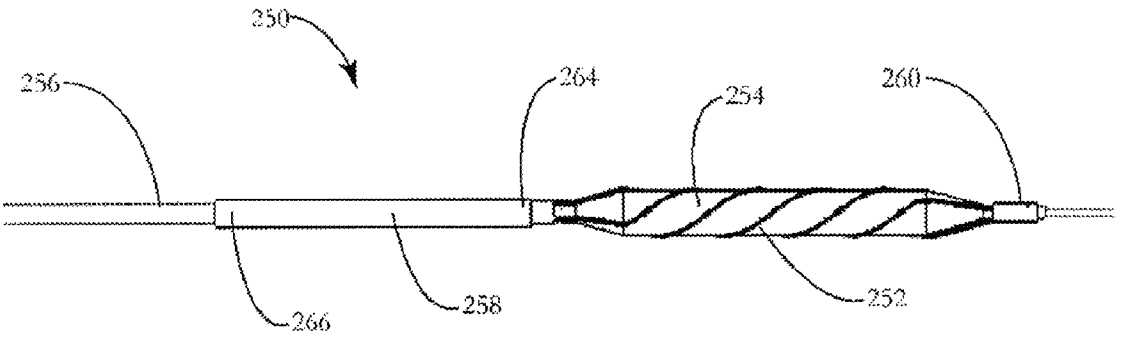


Fig. 17a

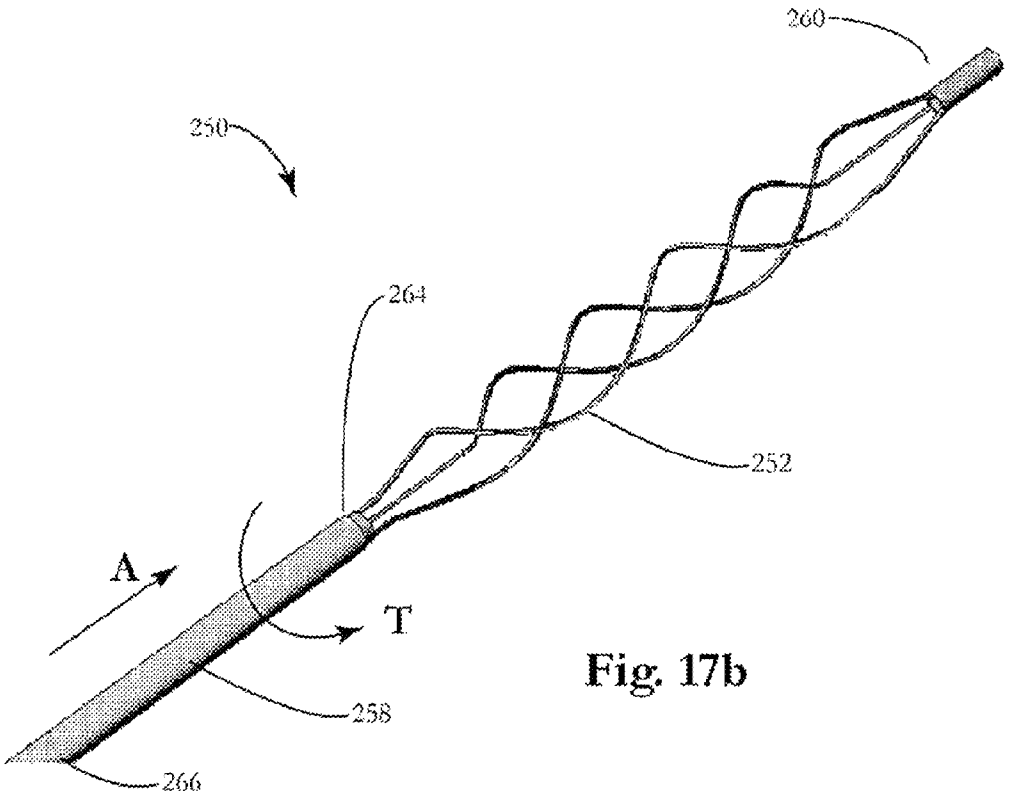


Fig. 17b

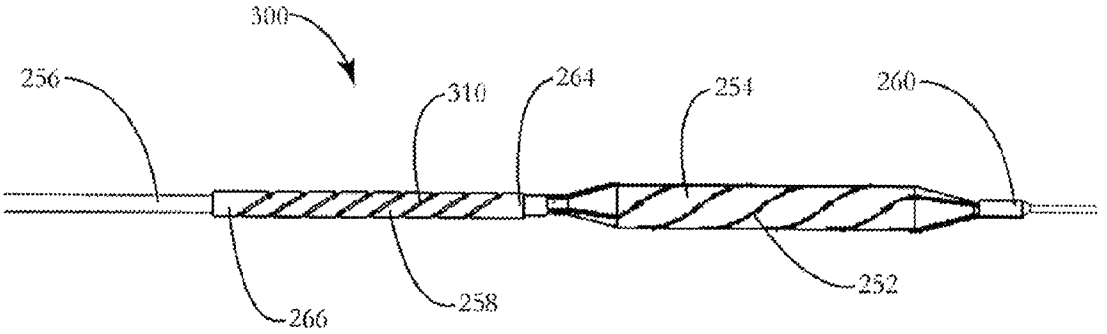


Fig. 18a

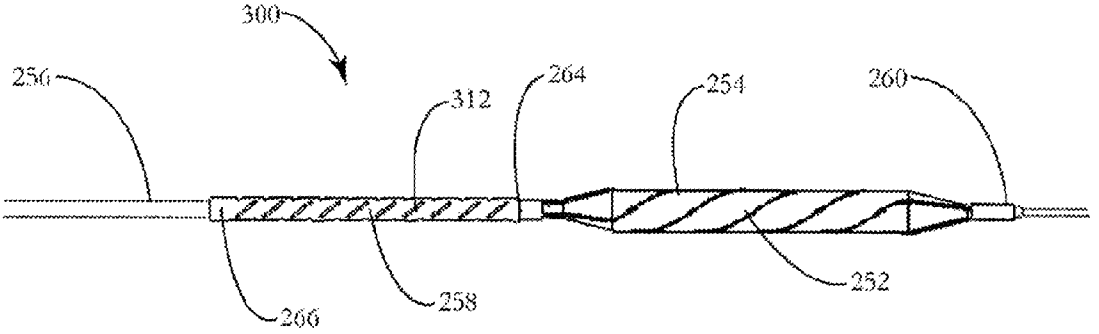


Fig. 18b

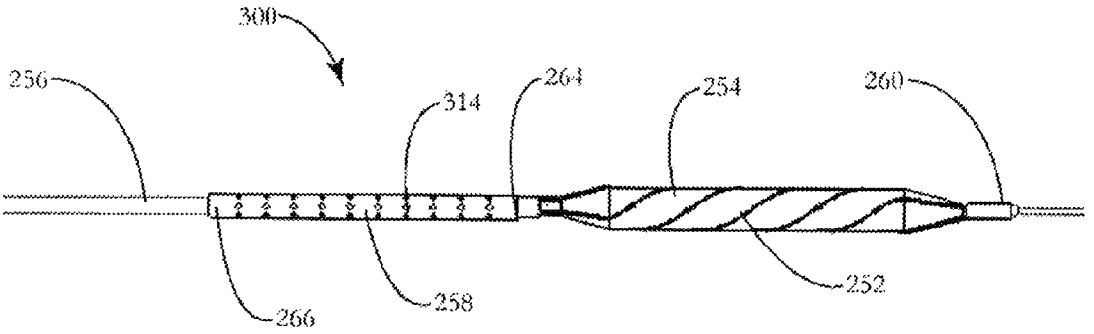
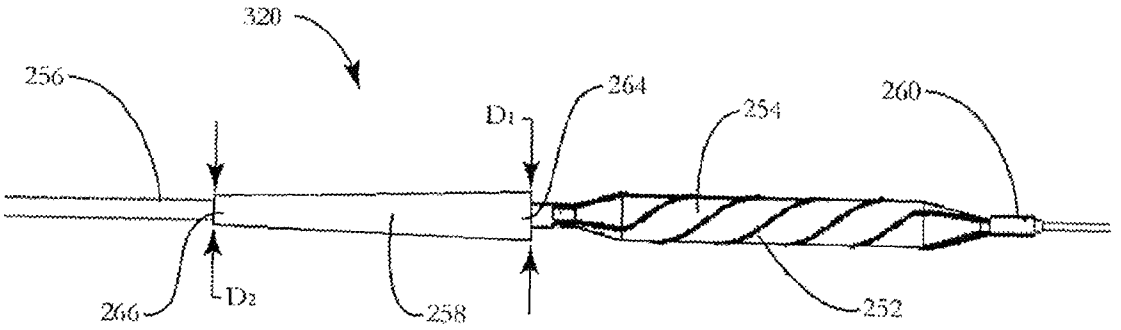


Fig. 18c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264
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260
D1
D2
266
258
252

Fig. 19

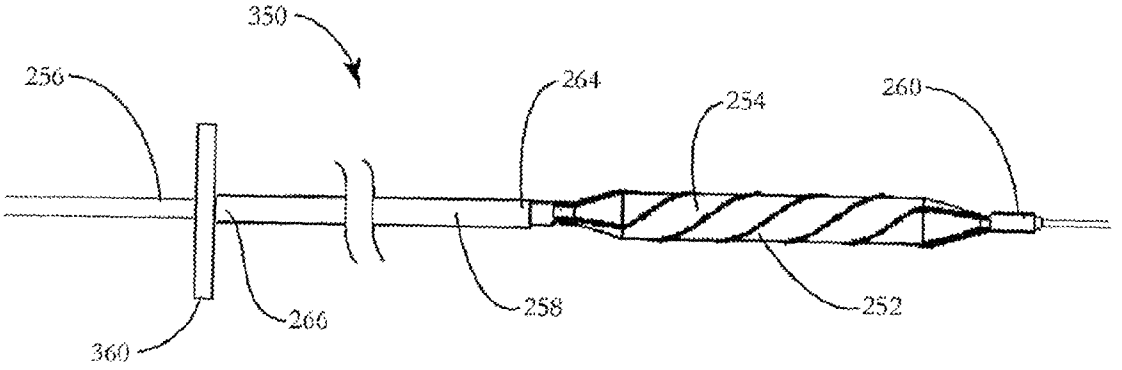
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Fig. 20

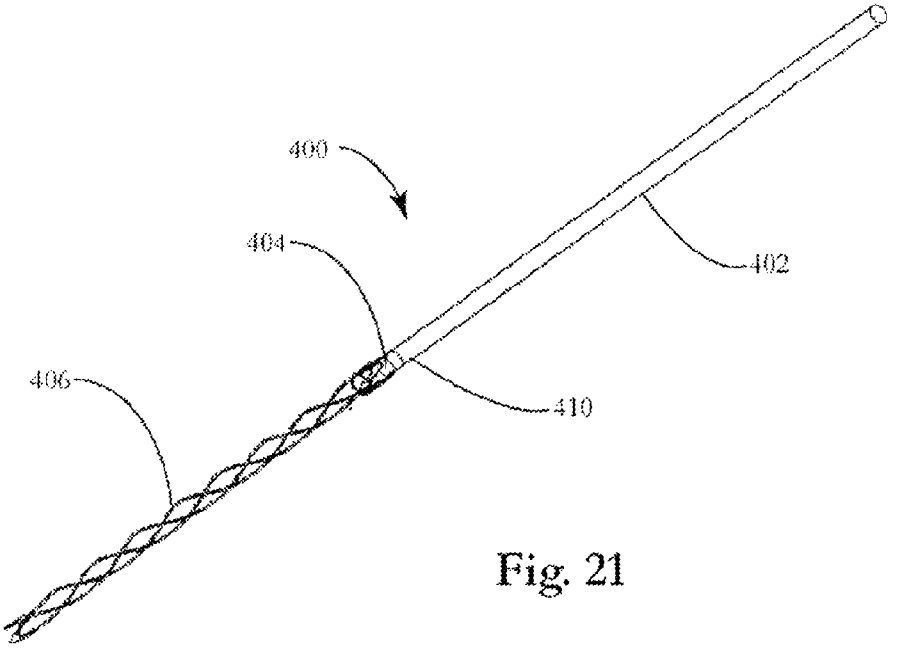

Fig. 21

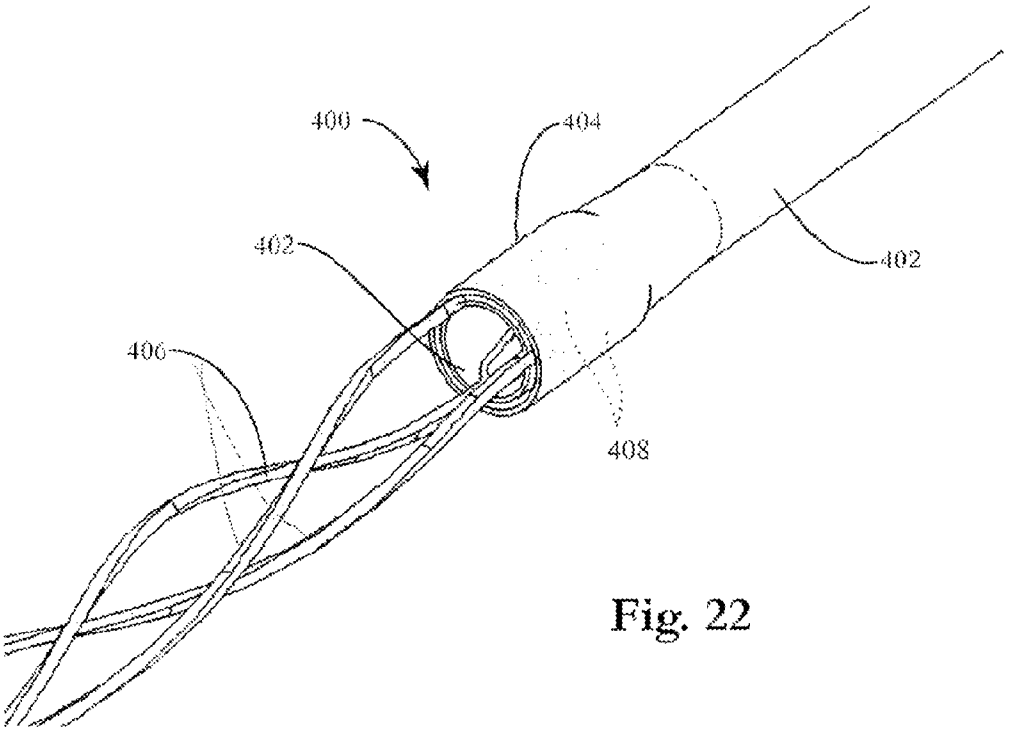

Fig. 22

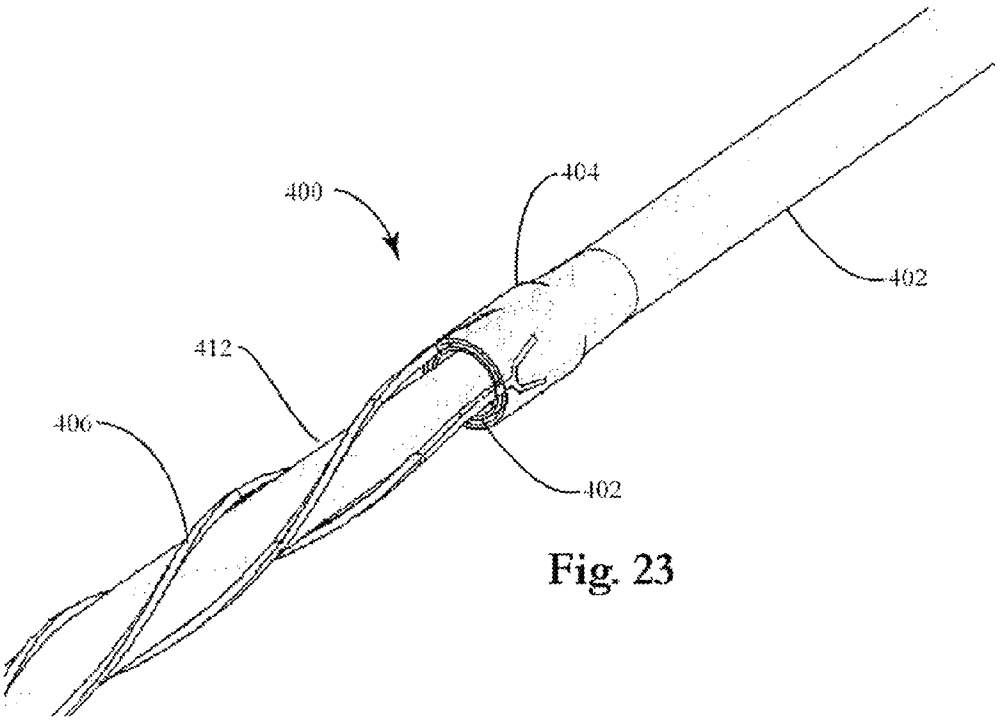

Fig. 23

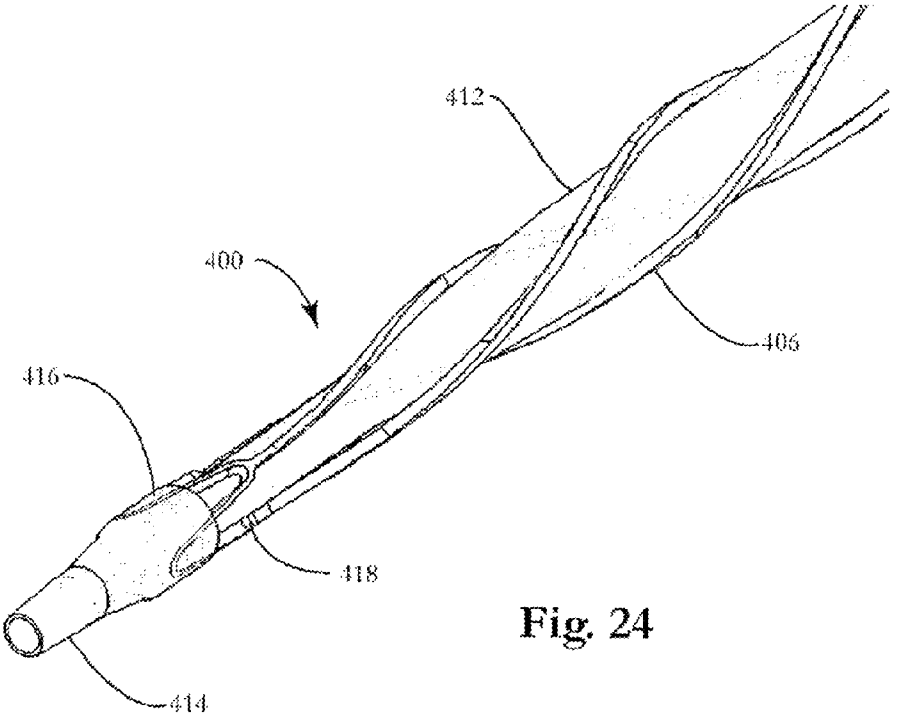

Fig. 24

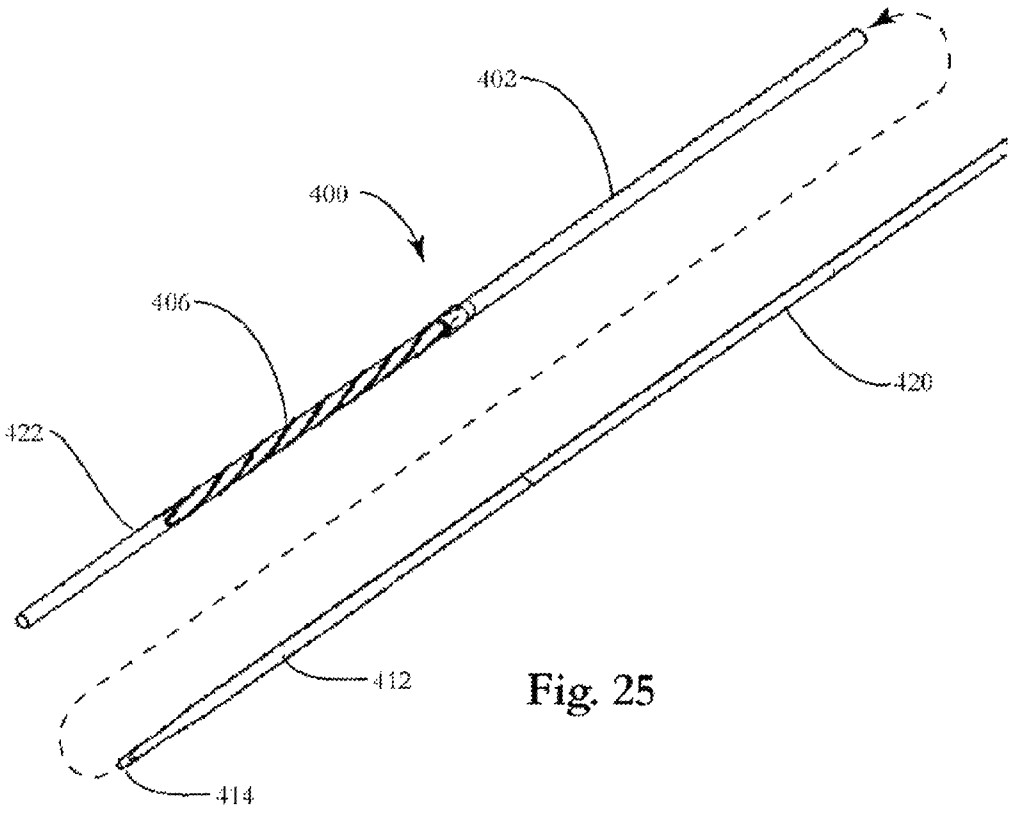

Fig. 25

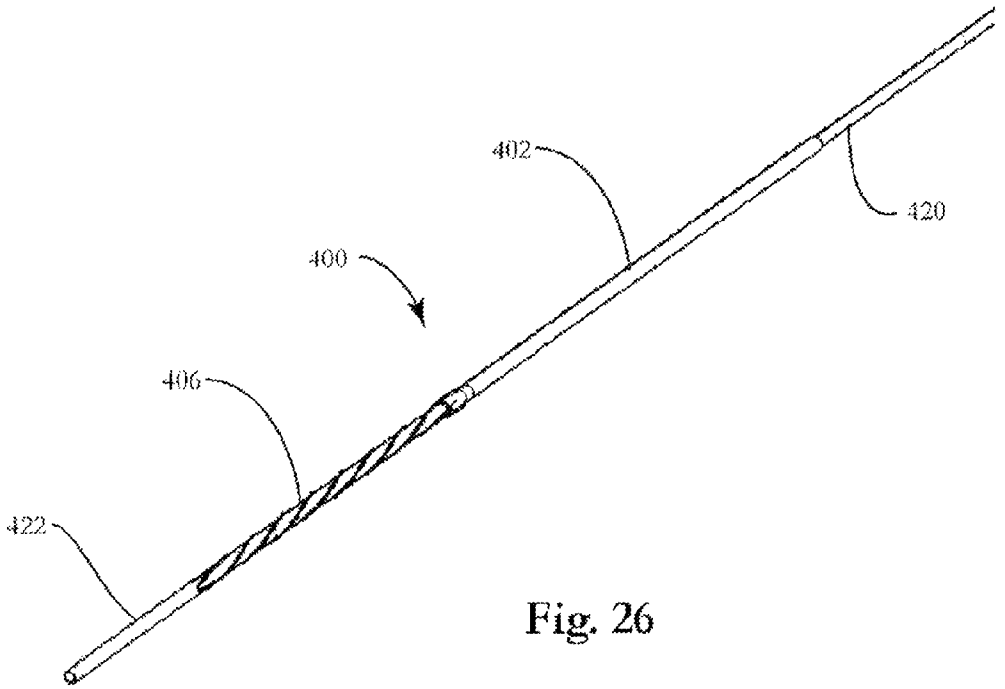

Fig. 26

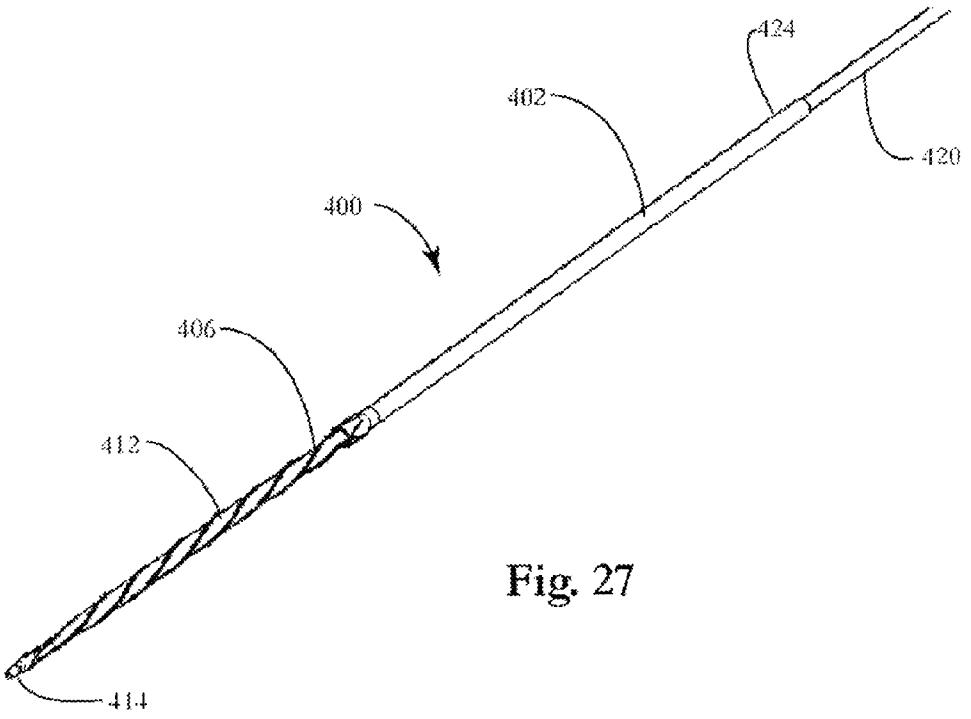

Fig. 27

APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is continuation of U.S. patent application Ser. No. 10/917,917, filed on Aug. 13, 2004, which is a continuation-in-part of commonly assigned, U.S. application Ser. No. 10/810,330, filed on Mar. 25, 2004 (now U.S. Pat. No. 7,955,350), which is a continuation-in-part of U.S. application Ser. No. 10/631,499, filed on Jul. 30, 2003 (now U.S. Pat. No. 7,686,824), which claims the benefit under 35 USC §119(e) of U.S. Provisional Application No. 60/442,161, filed on Jan. 21, 2003, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the field of medical devices, more specifically to medical devices intended to treat stenoses in the vascular system.

Balloon dilatation (angioplasty) is a common medical procedure mainly directed at revascularization of stenotic vessels by inserting a catheter having a dilatation balloon through the vascular system. The balloon is inflated inside a stenosed region in a blood vessel in order to apply radial pressure to the inner wall of the vessel and widen the stenosed region to enable better blood flow.

In many cases, the balloon dilatation procedure is immediately followed by a stenting procedure where a stent is placed to maintain vessel patency following the angioplasty. Failure of the angioplasty balloon to properly widen the stenotic vessel, however, may result in improper positioning of the stent in the blood vessel. If a drug-eluting stent is used, its effectiveness may be impaired by such improper positioning and the resulting restenosis rate may be higher. This is a result of several factors, including the presence of gaps between the stent and the vessel wall, calcified areas that were not treated properly by the balloon, and others.

Conventional balloon angioplasty suffers from a number of other shortcomings as well. In some cases the balloon dilatation procedure causes damage to the blood vessel due to aggressive balloon inflation that may stretch the diseased vessel beyond its elastic limits. Such over inflation may damage the vessel wall and lead to restenosis of the section that was stretched by the balloon. In other cases, slippage of the balloon during the dilatation procedure may occur. This may result in injury to the vessel wall surrounding the treated lesion. One procedure in which slippage is likely to happen is during treatment of in-stent restenosis, which at present is difficult to treat by angioplasty balloons. Fibrotic lesions are also hard to treat with conventional balloons, and elastic recoil is usually observed after treatment of these lesions. Many long lesions have fibrotic sections that are difficult to treat using angioplasty balloons.

An additional problem associated with balloon angioplasty treatment has been the "watermelon seed effect." Angioplasty is carried out at very high pressures, typically up to twenty atmospheres or higher, and the radially outward pressure of the balloon can cause axial displacement of the balloon in a manner similar to squeezing a watermelon seed with the fingers. Such axial displacement, of course, reduces the effectiveness of balloon dilatation. Another problem with conventional angioplasty balloon design has been deflation of the balloon. Even after the inflation medium is removed from a balloon, the deflated configuration will have a width greater than the original folded configuration which was introduced to the vasculature. Such an increase in profile can make removal of the balloon difficult.

Atherectomy/Thrombectomy devices intended to remove plaque/thrombus material may also include a structure that expands in a lesion while the plaque/thrombus removal mechanism is within this structure. The removed material is either being stacked in the catheter or sucked out thru the catheter. When the procedure is done, the expandable structure is collapsed and the catheter removed. Foreign object removal devices usually include a basket structure that needs to be expanded to collect the object and then collapse for retrieval. Distal protection devices usually include a basket structure that support a mesh that needs to be expanded distal to the treated lesion to collect the loose objects and then collapse for retrieval.

These devices usually include an elastic metallic material that needs to be expanded in the vascular system to fulfill its task and afterwards collapse to a small diameter to facilitate retrieval. The transition between the collapsed (closed) configuration to the expanded (open) configuration can be done in two ways: the structure can be at a normally closed (collapsed) configuration in which force is applied to cause the structure to expand. In this case, the elastic recoil of the structure will cause it to collapse back to closed configuration when the expanding force ceases. The structure may also be at a normally open (expanded) configuration in which a constraining element is forced over it to hold it down for the collapsed configuration (for example a constraining tube). When this constraining element is removed the structure is free to expand to the expanded (open) configuration. The structure material may also be non elastic. In this case, the structure will need to be forced to transit between both collapsed and expanded configurations.

One problem associated with conventional angioplasty expansion systems is that the transition between the collapsed and expanded configurations involves significant rotational and axial reaction forces. These reaction forces are applied by the structure on the catheter as a result of the force applied by the catheter to expand or close the structure. Axial reaction forces are created due the foreshortening of the structure during expansion. Rotational reaction forces (torques) are created when a non longitudinal element is forced to expand/collapse. Since the catheters are usually less stiff than the structure, these reaction forces may cause the structure to not expand or collapse properly, or cause undesired deformation to the catheter itself.

To overcome at least some of these problems these problems, U.S. Pat. No. 5,320,634 describes the addition of cutting blades to the balloon. The blades can cut the lesions as the balloon is inflated. U.S. Pat. No. 5,616,149 describes a similar method of attaching sharp cutting edges to the balloon. U.S. Patent Publication 2003/0032973 describes a stent-like structure having non-axial grips for securing an angioplasty balloon during inflation. U.S. Pat. No. 6,129,706 describes a balloon catheter having bumps on its outer surface. U.S. Pat. No. 6,394,995 describes a method of reducing the balloon profile to allow crossing of tight lesions. U.S. Patent Publication 2003/0153870 describes a balloon angioplasty catheter having a flexible elongate elements that create longitudinal channels in a lesion or stenosis.

While the use of angioplasty balloons having cutting blades has proved to be a significant advantage under many circumstances, the present cutting balloon designs and methods for their use continue to suffer from shortcomings. Most

commercial cutting balloon designs, including those available from InterVentional Technologies, Inc., of San Diego, Calif., now owned by Boston Scientific, of Natick, Mass., have relatively long, axially aligned blades carried on the outer surface of an angioplasty balloon. Typically, the blades are carried on a relatively rigid base directly attached to the outer balloon surface. The addition of such rigid, elongated blade structures makes the balloon itself quite stiff and limits the ability to introduce the balloon through torturous regions of the vasculature, particularly the smaller vessels within the coronary vasculature. Moreover, the cutting balloons can be difficult to deflate and collapse, making removal of the balloons from the vasculature more difficult than with corresponding angioplasty balloons which do not include cutting blades. Additionally, the axially oriented cuts imparted by such conventional cutting balloons do not always provide the improved dilatation and treatment of fibrotic lesions which would be desired.

For these reasons, it would be desirable to provide improved cutting balloon designs and methods for their use. In particular, it would be desirable to provide cutting balloons which are highly flexible over the length of the balloon structure, which readily permit deflation and facilitate removal from the vasculature, and which are effective in treating all forms of vascular stenoses, including but not limited to treatment of highly calcified plaque regions of diseased arteries, treatment of small vessels and/or vessel bifurcations that will not be stented, treatment of ostial lesions, and treatment of in-stent restenosis (ISR). Moreover, it would be desirable if such balloon structures and methods for their use could provide for improved anchoring of the balloon during dilatation of the stenosed region.

It would further be desirable to minimize the reaction forces applied by the external structure to the catheter, and at the same time be able to control the expansion of the expandable structure. It would also be desirable to adjust the compliance of the system in a predictable way without changing the materials or geometry of the expandable structure. At least some of these objectives will be met with the inventions described hereinafter.

2. Description of the Background Art

The following U.S. patents and printed publication relate to cutting balloons and balloon structures: U.S. Pat. Nos. 6,450,988; 6,425,882; 6,394,995; 6,355,013; 6,245,040; 6,210,392; 6,190,356; 6,129,706; 6,123,718; 5,891,090; 5,797,935; 5,779,698; 5,735,816; 5,624,433; 5,616,149; 5,545,132; 5,470,314; 5,320,634; 5,221,261; 5,196,024; and Published U.S. Pat. App. 2003/0032973. Other U.S. patents of interest include U.S. Pat. Nos. 6,454,775; 5,100,423, 4,998,539; 4,969,458; and 4,921,984.

SUMMARY OF THE INVENTION

The present invention provides improved apparatus and methods for the dilatation of stenosed regions in the vasculature. The stenosed regions will often include areas of fibrotic, calcified, or otherwise hardened plaque or other stenotic material of the type which can be difficult to dilatate using conventional angioplasty balloons. The methods and apparatus will often find their greatest use in treatment of the arterial vasculature, including but not limited to the coronary arterial vasculature, but may also find use in treatment of the venous and/or peripheral vasculature, treatment of small vessels and/or vessel bifurcations that will not be stented, treatment of ostial lesions, and treatment of ISR.

In a first aspect of the present invention, a scoring catheter comprises a catheter body having a proximal end and a distal end, a radially expandable shell (typically an angioplasty balloon) near the distal end of the catheter body, and a non-axial scoring structure carried over the shell. By "non-axial scoring structure," it is meant that the structure will be able to score or cut stenotic material within a treated blood vessel along lines which are generally in a non-axial direction. For example, the scoring lines may be helical, serpentine, zig-zag, or may combine some axial components together with such non-axial components. Usually, the non-axial scoring pattern which is imparted will include scoring segments which, when taken in total, circumscribe at least a majority of and usually the entire inside wall of the blood vessel up to one time, preferably more than one time, usually more than two times, often at least three times, more often at least four, five, six, or more times. It is believed that the resulting scoring patterns which circumscribe the inner wall of the vessel will provide improved results during subsequent balloon dilatation.

Usually the scoring structure will comprise at least one continuous, i.e., non-broken, scoring element having a length of at least 0.5 cm, more usually at least 1 cm, often at least 2 cm, usually at least 3 cm, and sometimes at least 4 cm or more. Alternatively, the scoring structure may comprise a plurality of much smaller segments which may be arranged in a helical or other pattern over the balloon, typically having a length in the range from 0.1 cm to 2 cm, often being 0.5 cm or less, sometimes being 0.3 cm or less.

In order to promote scoring of the blood vessel wall when the underlying expandable shell is expanded, the scoring structure will usually have a vessel contact area which is 20% or less of the area of the expandable shell, usually being below 10%, and often being in the range from 1% to 5% of the area of the expandable shell. The use of a shell having such a relatively small contact area increases the amount of force applied to the vascular wall through the structure by expansion of the underlying expandable shell. The scoring structure can have a variety of particular configurations, often being in the form of a wire or slotted tube having a circular, square, or other cross-sectional geometry. Preferably, the components of the scoring structure will comprise a scoring edge, either in the form of a honed blade, a square shoulder, or the like. A presently preferred scoring edge is electropolished and relatively small.

In a preferred embodiment, the scoring structure may be formed as a separate expandable cage which is positioned over the expandable shell of the catheter. The cage will usually have a collar or other attachment structure at each end for placement on the catheter body on either side of the expandable shell. A collar may be a simple tube, and other attachment structures will usually be crimpable or otherwise mechanically attachable to the catheter body, such as a serpentine or other ring structure. The attachment structures on the cage may be attached at both ends to the catheter body, but will more usually be attached at only a single end with the other end being allowed to float freely. Such freedom allows the scoring structure to shorten as the structure is expanded on the expandable shell. In certain embodiments, both ends of the scoring structure will be fixed to the catheter body, but at least one of the attachment structures will have a spring or other compliant attachment component which provides an axial extension as the center of the scoring structure foreshortens.

In many cases, since the scoring elements are non-axial, there are torques induced during the expansion of the balloon and the shortening of the scoring structure. These torques may be high, and if one end of the scoring structure is constrained from rotation, the scoring element will not expand

properly. The final expanded configuration of the scoring element is achieved via shortening and rotation.

In a preferred embodiment, both sides of the scoring element are fixed to the catheter, but at least one side will have a compliant structure which will provide axial tension and at the same time will allow the scoring element to rotate to its final configuration.

In some cases both ends of the scoring element are fixed and the shortening is achieved by deformation of the wire. For example, the wire can have a secondary structure which permits elongation (e.g., it may be a coiled filament) or can be formed from a material which permits elongation, e.g., nitinol. The scoring element can be attached in both ends, in a way that will allow rotation. In the case were the torques are low (depending on the design of the scoring element) there is no need for rotation and the torque can be absorbed either by the scoring element or by the catheter.

In all cases, the scoring structure is preferably composed of an elastic material, more preferably a super elastic material, such as nitinol. The scoring structure is thus elastically expanded over the expandable shell, typically an inflatable balloon similar to a conventional angioplasty balloon. Upon deflation, the scoring structure will elastically close to its original non-expanded configuration, thus helping to close and contain the balloon or other expandable shell.

In some cases the scoring element will be a combination of more than one material. In one case the scoring element can be made from nitinol and parts of it can be made from stainless steel. In other cases the scoring element can be made of stainless steel or nitinol and part of it can be made from polymer to allow high deformations.

In other preferred embodiments, the assembly of the shell and the scoring structure will be sufficiently flexible to permit passage through tortuous regions of the vasculature, e.g., being capable of bending at radius of 10 mm or below when advanced through 45°, 90° or higher bends in the coronary vasculature. Usually, the scoring structure will comprise one or more scoring elements, wherein less than 70% of the cumulative length of the scoring element is aligned axially on the shell when expanded, preferably being less than 50% of the cumulative length, and more preferably being less than 25% of the cumulative length. In other instances, the scoring structure may comprise one or more scoring elements, wherein the cumulative length of the scoring element includes a non-axial component of at least 10 mm, preferably at least 12 mm, and more preferably 36 mm. Preferably, at least some of the scoring elements will have scoring edges which are oriented radially outwardly along at least a major portion of their lengths at all times during inflation and deflation and while inflated. By "radially outward," it is meant that a sharp edge or shoulder of the element will be oriented to score or cut into the stenotic material or the interior wall of the treated vessel, particularly as the shell is being inflated.

The scoring elements will usually, but not necessarily, have a scoring edge formed over at least a portion of their lengths. A "scoring edge" may comprise a sharpened or honed region, like a knife blade, or a square shoulder as in scissors or other shearing elements. Alternatively, the scoring elements may be free from defined scoring edges, e.g., having circular or the other non-cutting profiles. Such circular scoring elements will concentrate the radially outward force of the balloon to cause scoring or other disruption of the plaque or other stenotic material being treated.

In a second aspect of the present invention, the scoring catheter comprises a catheter body and a radially expandable shell, generally as set forth above. The scoring structure will be composed of elements which circumscribe the radially expandable shell. By "circumscribing the radially expandable shell," it is meant that at least some scoring elements of the scoring structure will form a continuous peripheral path about the exterior of the expandable shell during expansion. An example of such a fully circumscribing structure is a helical structure which completes up to one 360° path about the balloon before, during and after expansion, usually completing two complete revolutions, and frequently completing three, four, or more complete revolutions. Exemplary helical structures may include two, three, four, or more separate elements, each of which is helically arranged around the radially expandable shell.

In a third aspect of the present invention, a scoring catheter comprises a catheter body and a radially expandable shell, generally as set forth above. An elongated scoring structure is carried over the shell, and the assembly of the shell and the scoring structure will be highly flexible to facilitate introduction over a guide wire, preferably being sufficiently flexible when unexpanded so that it can be bent at an angle of at least 90°, preferably 180°, at a radius of 1 cm without kinking or otherwise being damaged. Such flexibility can be determined, for example, by providing a solid cylinder having a radius of 1 cm and conforming the assembly of the scoring structure and expandable shell over the cylinder. Alternatively, the assembly can be advanced over a guide wire or similar element having a 180° one centimeter radius bend. In either case, if assembly bends without kinking or other damage, it meets the requirement described above. Other specific features in this further embodiment of the catheters of the present invention are as described above in connection with the prior embodiments.

In a fourth aspect of the present invention, a plaque scoring catheter comprises a catheter body and a radially expandable balloon, generally as set forth above. A plurality of scoring elements are distributed over the balloon, typically being attached directly to an outer surface of the balloon. The scoring elements will be relatively short, typically having lengths below about 25% of the balloon length, preferably having lengths in the range from 2% to 10% of the balloon length. The relatively short, segmented scoring elements will permit highly flexible assemblies of balloon and scoring elements, generally meeting the flexibility requirement set forth above. The scoring elements may be arranged randomly over the balloon but will more usually be distributed uniformly over the balloon. In specific embodiments, the scoring elements may be arranged in helical, serpentine, or other regular patterns which circumscribe the balloon. As the balloon expands, such short segments will generally move apart from each other, but will still impart the desired scoring patterns into the vascular wall as the balloon is inflated.

In a fifth embodiment, the scoring catheter according to the present invention comprises a catheter body and a radially expandable balloon generally as set forth above. The balloon has a plurality of lobes extending between ends of the balloons, and at least one scoring element will be formed on at least one of the lobes in a manner arranged to score stenotic material as the balloon is expanded. The lobe will usually be in a helical pattern, and typically two, three, or more lobes will be provided. In the case of helical lobes, the scoring element(s) will usually be disposed along a helical peak defined by the helical lobe when the balloon is inflated. Such helical scoring elements will be arranged to accommodate balloon inflation, typically being stretchable, segmented, or the like.

In still another aspect of the apparatus of the present invention, an expandable scoring cage is adapted to be carried over a balloon of a balloon catheter. The scoring cage comprises an

assembly of one or more elongate elastic scoring elements arranged in a non-axial pattern. As defined above, the non-axial pattern may comprise both axial and non-axial segments. The assembly is normally in a radially collapsed configuration and is expandable over a balloon to a radially expanded configuration. After the balloon is deflated, the assembly returns to a radially collapsed configuration, preferably being assisted by the elastic nature of the scoring cage. Advantageously, the scoring cage will enhance uniform expansion of the underlying balloon or other expandable shell and will inhibit "dog boning" where an angioplasty balloon tends to over inflate at each end, increasing the risk of vessel dissection. The scoring elements will be adapted to score hardened stenotic material, such as plaque or fibrotic material, when expanded by the balloon in a blood vessel lumen. The scoring cage may be adapted to mount over the balloon with either or both ends affixed to the balloon, generally as described above in connection with prior embodiments. Preferred geometries for the scoring elements include those which circumscribe the balloon, those which are arranged helically over the balloon, those which are arranged in a serpentine pattern over balloon and the like.

In yet another aspect of the present invention, a method for dilatating a stenosed region in a blood vessel comprises radially expanding a shell which carries a scoring structure. The scoring structure scores and dilates the stenosed region and includes one or more non-axial scoring elements arranged to impart a circumscribing score pattern about the inner wall of the blood vessel as the shell is expanded. The stenosed region is typically characterized by the presence of calcified plaque, fibrotic plaque, or other hardened stenotic material which is preferably scored prior to dilatation. Preferably, the scoring structure will not be moved in axial direction while engaged against the stenosed region, and the scoring structure may optionally be free from axially scoring elements.

In still another aspect of the present invention, an angioplasty catheter comprises a catheter body and a radially expandable shell near the distal end of the catheter body. An external structure, such as a scoring structure or cutting structure, is carried over but unattached to the shell. The catheter further comprises an attachment structure having a proximal end and a distal end attached to the scoring structure, wherein the attachment structure is sufficiently sized and compliant to accommodate reaction forces or geometrical changes produced by the scoring structure as it is expanded by the shell. Generally, at least a portion of said scoring structure is arranged helically over the shell. However, the scoring structure may comprise numerous different configurations as described above.

In one aspect of the present invention, the proximal end of the attachment structure is fixed to the catheter body and the distal end of the attachment structure is secured to the proximal end of the scoring structure. In all cases, the attachment structure is capable axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In a preferred embodiment, the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body. The inner diameter of the compliance tube is generally larger than an outer diameter of the catheter body so that the compliance tube freely extends and/or rotates with respect to the catheter body as the scoring structure foreshortens.

The compliance tube may also be sized to control the compliance of the scoring structure and expandable shell. Generally, the compliance tube has wall thickness ranging from 0.001 in to 0.1 in., preferably 0.005 in. to 0.05 in. The wall thickness may be increased to lessen the compliance of the system, or decreased to create a greater compliance. The length of the compliance tube may also be adjusted to control the compliance of the system. Generally, compliance tube has a length ranging from 1 cm to 10 cm, but may range up to 30 cm or more for embodiments wherein the tube extends across the length of the catheter body.

In most cases, the material of the compliance tube may also be selected to control the compliance of the scoring structure and expandable shell. Generally, the compliance tube comprises an elastic material, preferably a polymer such as nylon or Pebax™. Alternatively, the compliance tube may comprise a braided material, metal or wire mesh.

In some aspects of the present invention, the compliance tube may have one or more perforations to control the compliance of the scoring structure and expandable shell. Generally, the perforations comprise one or more slots extending along the outside circumference of the compliance tube. The slots may form a pattern along the outside circumference of the compliance tube. The slots may be parallel to each other, and/or extend helically or radially across the circumference of the compliance tube. The slots themselves may be formed of a variety of shapes, such as circular or rectangular.

Preferably, compliance tube has an outer diameter that tapers from its distal end to its proximal end so that the outside diameter at the proximal end is slightly larger than the inner diameter, and the outside diameter at the distal end is sized to approximate the diameter of the scoring structure when in a collapsed configuration. This allows for the catheter to be readily removed from a vessel without catching or snagging on the vessel wall. For the tapered configuration, the outer diameter of the compliance tube will vary depending on the size of the catheter body and the expansion cage, but the diameter generally tapers down in the range of 0.004 in to 0.010 in. from the distal end to the proximal end.

In another aspect of the invention, the attachment structure is connected at its distal end to the scoring structure and at its proximal end to a manipulator. Typically, the manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the scoring structure across the length of the catheter body. In all cases, the attachment structure is capable of axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In a preferred embodiment, the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body. Typically, the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely extends and rotates with respect to the catheter body as the scoring structure foreshortens. The compliance of the scoring structure and expandable shell may be controlled by adjusting the thickness, length, or material selection of the compliance tube.

In some embodiments, the compliance of the scoring structure is controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. Specifically, the attachment structure may be axially advanced with respect to the catheter body as the balloon is being inflated or deflated. For example, the attachment structure may be pulled away from the distal end of the catheter body while the balloon is being expanded to constrain the compliance of balloon. Alternatively, the manipulator may be used to rotate the attachment structure with respect to the catheter body to control the compliance of the balloon during transition.

In another embodiment of the present invention, a method of dilatating a stenosed region in a blood vessel comprises

introducing a scoring structure carried over an expandable shell that is connected to a catheter body by an attachment structure, and expanding the scoring structure within a stenosed region within the blood vessel. In this method, the attachment structure axially and/or rotationally extends to accommodate foreshortening of the scoring structure as the shell is expanded. The attachment structure generally comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body, wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely extends and rotates with respect to the catheter body as the scoring structure foreshortens. The thickness, length, and material of the compliance tube may be selected to control the compliance of the scoring structure and expandable shell.

In some embodiments, the method further comprises the step of fixing the proximal end of the attachment structure to the catheter body. Alternatively, the method may comprise the step of fixing the proximal end of the attachment structure to a manipulator. In such an embodiment, manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the scoring structure across the length of the catheter body. This allows for the compliance of the scoring structure and balloon to be controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. Actuation of the manipulator may occur by axially advancing, pulling or rotating the attachment structure with respect to the catheter body.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**, **1**A, **1**B and **1**C are schematic illustrations of the balloon scoring structure embodiment in accordance with an embodiment of the invention.

FIG. **2** is a schematic illustration of an exemplary helical scoring structure embodiment in accordance with embodiments of the invention.

FIG. **3** is a schematic illustration of an expanded angioplasty balloon carrying a helical scoring structure in accordance with embodiments of the invention.

FIG. **4** illustrates a scoring structure comprising an alternating serpentine pattern of intermediate scoring elements between a pair of end collars.

FIG. **5** illustrates the serpentine scoring elements of the embodiment of FIG. **4** shown in a rolled-out configuration.

FIG. **6** illustrates a scoring structure comprising alternating C-shaped scoring elements between a pair of end collars.

FIG. **7** illustrates the C-shaped scoring elements of the embodiment of FIG. **6** shown in a rolled-out configuration.

FIG. **8** is a view of one of the C-shaped scoring elements taken along line **8**-**8** of FIG. **6**.

FIG. **9** illustrates an alternative double C-shaped scoring element which could be utilized on a scoring structure similar to that illustrated in FIG. **6**.

FIG. **10** illustrates an alternative embodiment of a helical scoring structure comprising serpentine and zigzag structures for mounting onto a balloon catheter.

FIG. **11** illustrates a first of the serpentine mounting elements of the scoring structure of FIG. **10**.

FIG. **12** illustrates a second of the serpentine mounting elements of the scoring structure of FIG. **10**.

FIG. **13** illustrates an alternative mounting structure for a helical or other scoring structure.

FIG. **14** illustrates the mounting structure of FIG. **13** shown in a rolled-out configuration.

FIG. **15** shows yet another embodiment of a mounting element for the scoring structures of the present invention.

FIG. **16** illustrates the mounting structure of FIG. **15** shown in a rolled-out configuration.

FIG. **17***a* illustrates yet another alternative embodiment of a catheter constructed in accordance with the principles of the present invention, where an attachment structure is disposed between the scoring structure and the catheter body.

FIG. **17***b* illustrates the structure of FIG. **17***a* shown without the balloon.

FIGS. **18***a-c* illustrate a catheter constructed in accordance with the principles of the present invention having an attachment structure with various patterned perforations.

FIG. **19** illustrates another embodiment of a catheter constructed in accordance with the principles of the present invention having a tapered attachment structure.

FIG. **20** illustrates yet another alternative embodiment of a catheter constructed in accordance with the principles of the present invention, where an attachment structure is connected to a manipulator.

FIG. **21** illustrates an embodiment of the invention having a laminated section at the distal end of the compliance tube.

FIG. **22** illustrates another view of the embodiment of FIG. **21**.

FIG. **23** illustrates the embodiment of FIG. **21** with an expandable balloon inserted within the scoring structure.

FIG. **24** illustrates an embodiment with a sleeve over the distal end of the scoring structure.

FIG. **25** illustrates a method of the present invention utilizing an insertion tube to mount the scoring structure over the expandable balloon.

FIG. **26** illustrates shows the insertion tube inserted over the expandable balloon.

FIG. **27** illustrates a scoring catheter of the present invention with the insertion tube removed.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well-known features may be omitted or simplified in order not to obscure the present invention.

Embodiments of the present invention relate to device for revascularization of stenotic vessels and specifically to a balloon catheter having external elements. The dilatation device comprises a conventional dilatation balloon such as a polymeric balloon and a spiral, or external elements with other configurations mounted on the balloon catheter.

Reference is now made to FIGS. **1**, **1**A and **1**B, which are schematic illustrations of a dilatation device **10** in accordance with embodiments of the invention. The dilatation device **10** includes a dilatation balloon **12**, which may be any conventional angioplasty balloon such as commonly used by interventional cardiologists or radiologists, and a helical or spiral unit **14** mounted over or attached to dilatation balloon **12**. The compliance of the balloon and the scoring element(s) should be chosen to assure uniform expansion of the balloon substantially free from "dog-boning" as the combined structure expands within a lesion. If a compliant or a semi-compliant balloon is used and the compliance of the scoring element was not matched to comply with the properties of the balloon, the expansion of the balloon-scoring element system will not be

uniform. This non-uniformity may impair the efficacy of the scoring catheter and, in some cases, may result in poor performance. For example, under given pressure, certain parts of the balloon will be able to expand while other parts will be constrained by excessive resistance of the scoring elements.

Helical unit **14** is typically made of nitinol. Helical unit **14** may be made of other metals such stainless steel, cobalt-chromium alloy, titanium, and the like. Alternatively, spiral unit **14** may be a polymeric spiral, or made of another elastic material. Helical unit **14** may be attached at its proximal and distal ends to the proximal end **17** and distal end **18** of dilatation balloon **12**. Alternatively, spiral unit **14** may be attached to the distal end and/or the proximal end of dilatation balloon **12** by collar-like attachment elements **15** and **16**. Spring or other compliant elements may be alternatively or additionally provided as part of the attachment elements to accommodate shortening of the helical unit as it is expanded.

Dilatation device **10** is inserted into the vascular system, for example, using a conventional catheter procedure, to a region of stenotic material **22** of blood vessel **20**. (The term "stenotic" is used herein to refer to the vascular lesion, e.g., the narrowed portion of the vessel that the balloon is meant to open.) At the stenotic area, the dilatation balloon **12** is inflated, for example, by liquid flow into the balloon. Helical unit **14** widens on the inflated dilatation balloon **12**. On inflation, the dilatation balloon **12** together with the helical unit **14** is pressed against the walls of blood vessel **20** as shown in FIG. **1**B.

Reference is now made to FIG. **1**C, illustrating blood vessel **20** after the deflation of dilatation balloon **12**. Helical unit **14** narrows when deflating the dilatation balloon **12**, thus the dilatation device **10** is narrowed and may be readily retrieved from blood vessel **20**. The deflation profile of the balloon **10** is low and mainly circular. The stenotic material **22** in blood vessel **20** is pressed against blood vessel **20** walls to widen the available lumen and enhance blood flow. The pressing of helical unit **14** against the walls of blood vessel **20** causes scoring **23** in the stenotic area.

Reference is now made to FIG. **3** that shows a scoring structure in the form of a single wire **24** wrapped around a dilatation balloon **12** in a helical configuration.

In other embodiments, the scoring structure of the present invention can have a non-helical configuration. Any design of scoring structure that can accommodate an increase in the diameter of the balloon **12** upon inflation, and return to its configuration when the balloon is deflated, is an appropriate design useful in the invention. At least a portion of the scoring elements will not be parallel to the longitudinal axis of the balloon catheter to enhance flexibility and improve scoring.

Referring again to FIGS. **1**A-**1**C, helical unit **14** is pushed outwardly by the inflation of the balloon **12**, and is stretched by the inflation of the balloon. When the balloon is deflated, helical unit **14** assists in the deflation by its elastic recoil. This active deflation is faster and also leads to a low profile of the deflated balloon. The balloon **12** is disposed within the helical unit **14**, which returns to its pre-inflated shape and forces the balloon to gain a low radial profile.

In another embodiment of the invention, dilatation device **10** may carry a stent. The stent can be crimped over the helical unit **14**. In this way, the helical unit **14** can push the stent against hard areas of the lesion, enabling proper positioning of the stent against the vessel wall, even in hard-calcified lesions without pre-dilation.

Reference is now made to FIG. **2**, illustrating the helical unit **14** in accordance with embodiments of the invention. Helical unit **14** is typically made of nitinol. Helical unit **14** includes three wires **19** that are attached to collars **15** and **16** at the proximal end and distal end, respectively. Alternatively the scoring structure may be formed as a metallic cage, which can be made from a slotted tube, or polymeric cage or polymeric external elements. Alternatively the scoring structure may comprise wires of other elements attached directly to the balloon material or close to the balloon ends.

Wires **19** (FIG. **2**) are attached between collars **15** and **16**. The diameter of the wires is typically in the range of 0.05 mm to 0.5 mm. Alternatively, a cage (for example a metallic cage made of a slotted tube) can be used in several configurations that allow local stress concentrations. The size and shape of the cross section of the cage elements or the cross section of the wires can vary. The cross section can be a circle, rectangle, triangle, or other shape.

In alternative embodiments, the wires **19** may comprise short segments that are attached to the balloon **12**.

In further alternative embodiments of the invention, the helical unit **14** may be glued, thermally bonded, fused or mechanically attached at one or both ends to dilatation balloon **12**.

In yet another embodiment, a scoring structure may comprise wires that are attached to the dilatation balloon **12** in helical configuration or other configuration. The wires may be thermally attached to the balloon **12**, glued, mechanically attached, or the like.

In still another embodiment, a scoring structure comprises wire or cage elements that are not parallel to the longitudinal axis of the balloon **12** so that the combination of the scoring structure **19** and the balloon **12** remains flexible.

In additional embodiments, the combination of dilatation balloon **12** and scoring structure scores the lesion and provides better vessel preparation for drug eluting stents by allowing better positioning of the stent against the vessel wall and diffusion of the drug through the scores in the lesion.

In these embodiments, the balloon can be used as a platform to carry drugs to the lesion where scoring of the lesion can enhance delivery of the drug to the vessel wall.

In these embodiments, the balloon can be used for a local drug delivery by embedding drug capsules, drug containing polymer, and the like, through the stenotic material and into the vessel wall.

From the above, it can be seen that the invention comprises catheters and scoring structures, where the scoring structures are positioned over the balloons or other expandable shells of the catheter. The scoring structures may be attached directly to the balloons or other shells, in some cases being embedded in the balloon material, but will more usually be formed as separate cage structures which are positioned over the balloon and attached to the catheter through attachment elements on either side of the balloon. The expandable cages may be formed using conventional medical device fabrication techniques, such as those used for fabricating stents, such as laser cutting of hypotube and other tubular structures, EDM forming of hypotubes and tubes, welding of wires and other components and the like.

Typically, such expandable shell structures will comprise the attachment elements and an intermediate scoring section between the attachment elements. As illustrated in the embodiments above, the attachment elements may be simple cylindrical or tube structures which circumscribe the catheter body on either side of the balloon or other expandable shell. The simple tube structures may float over the catheter body, i.e., be unattached, or may be fixed to the catheter body. A number of alternative embodiments for the attachment elements will be described in connection with the embodiments below.

The intermediate scoring sections may also have a variety of configurations where at least some of the scoring elements will typically be disposed in a non-axial configuration, i.e., in a direction which is not parallel to the axial direction of the expandable cage. A preferred configuration for the intermediate scoring section comprises one or more helical elements, generally as illustrated in the prior embodiments. Other exemplary configurations are set forth in the embodiments described below.

Referring now in particular to FIGS. **4** and **5**, an expandable scoring cage **100** comprises first and second attachment elements **102** and **104**, respectively, and an intermediate scoring section **106** comprising a plurality of curved serpentine members **110**. The serpentine members **110** extend circumferentially in opposite directions in an alternating manner. This can be understood by observing a "rolled-out" view of the serpentine elements as illustrated in FIG. **5**. A second alternative scoring cage structure **120** is illustrated in FIGS. **6-8**. The scoring cage **120** comprises first and second attachment elements **122** and **124** joined by a spine **126**. Plurality of C-shaped scoring elements **128** and **130** are attached to the spine and extend in opposite circumferential directions. The shape of the element can be observed in FIG. **8**. The opposite directions may be observed in the rolled-out view of FIG. **7**.

It will be appreciated that a variety of different circumferential structures may be used in place of the C-shaped structures of FIGS. **6-8**. For example, a pair of opposed C-shaped partial ring structures may be utilized, as illustrated in FIG. **9**. The C-shaped structures of FIG. **6** or the double C-shaped structures of FIG. **9** can also be extended so that they wrap around a balloon more than one time, either over or under the spine structure **126**.

The expandable cage structures **100** and **120** will each be mounted over a dilatation balloon, such as the balloon of FIGS. **1-3**, with the attachment elements secured to the catheter body on either side of the dilatation balloon. The tube or cylindrical attachment elements **102**, **104**, **122**, and **124** may simply float over the catheter body. In other embodiments, however, it may be desirable to use an adhesive or other means for affixing either one or both of the attachment elements to the catheter body. Having at least one floating attachment element, however, is often desirable since it can accommodate shortening of the intermediate scoring section as that section radially expands. In other cases, however, the individual scoring elements may possess sufficient elasticity to accommodate such shortening. For example, nitinol and other shape memory alloys possess significant stretchability, typically on the order of 8% which in some instances will be sufficient to accommodate any tension applied on the intermediate scoring section by radial expansion of the balloon.

Referring now to FIGS. **10-12**, alternative attachment elements are shown on an embodiment of an expandable scoring cage **140** comprising three helical scoring elements **142** which make up the intermediate scoring section. A first attachment element **146** comprises a single serpentine ring, as best illustrated in FIG. **11** while a second attachment element **148** comprises a pair of tandem serpentine rings **150** and **152**, as best illustrated in FIG. **12**. The use of such serpentine attachment structures is beneficial since it permits crimping of either or both of the structures onto the catheter body in order to fix either or both ends of the structure thereto. Usually, the single serpentine attachment structure **146** will be affixed to the catheter body while the double serpentine structure will be left free to allow movement of that end of the scoring cage to accommodate radial expansion of the underlying balloon.

Referring now to FIGS. **13** and **14**, a further alternative embodiment of an attachment element useful in the scoring cages of the present invention is illustrated. Attachment element **180** includes a pair of serpentine rings **182** and **184**, generally as shown in FIG. **13**, in combination with a coil spring structure **186** located between said rings **182** and **184**. The coil spring structure **186** includes three nested coil springs **190**, each joining one of the bend structures **192** and **194** on the serpentine rings **182** and **184**, respectively. The structure of the spring structure and adjacent serpentine rings can be understood with reference to the rolled-out configuration shown in FIG. **14**.

The attachment structure **180** is advantageous since it permits a fixed attachment of the outermost ring **182** to the underlying catheter body while the inner ring **184** remains floating and expansion and contraction of the intermediate scoring section, comprising helical elements **196**, is accommodated by the coil spring structure **186**. Since the scoring cage is fixed to the catheter, any risk of loss or slippage from the balloon is reduced while sufficient compliance is provided to easily accommodate radial expansion of the intermediate scoring section. By attaching the structures **180** at least one, and preferably both ends of the scoring cage, the risk of interference with a stent is reduced.

In some embodiments, collars, such as those shown in FIGS. **1** and **2**, or attachment elements, such as those shown in FIGS. **10-12**, may comprise a flexible material that allows the collar or attachment element to expand while being mounted over the balloon catheter and then be collapsed to the diameter of the catheter. The expandability of the collars and/or attachment elements may be achieved by a compliant memory material such as nitinol or a polymer, or by use of a flexible serpentine design as shown in FIGS. **10-12**. Where collars are used, the collar may be shaped or have a slit down the circumference (not shown) so that the collar may be expanded during mounting over the balloon. Alternatively, the collar may be oversized to accommodate the balloon diameter mounting, and then crimped down to secure the secure the scoring structure to the catheter body.

Yet another embodiment of the attachment element of the present invention includes an axial spring as shown in FIGS. **15** and **16**. The attachment element **200** includes a terminal serpentine ring **202** and an intermediate spring structure **204** including a number of axial serpentine spring elements **206**. The nature of the serpentine ring elements **206** can be observed in the rolled-out configuration of FIG. **16**. Optionally, a second serpentine ring **210** may be provided between the attachment structure **200** and the helical scoring elements of the intermediate scoring section **212**.

The embodiments of FIGS. **13-16** comprise spring-like elements **186** and **204** to accommodate axial shortening of the scoring structure upon radial expansion. It will be appreciated that other metal and non-metal axially extensible structures could also be used in such attachment structures. For example, elastic polymeric tubes could be attached at one end to the scoring structures and at another end to the catheter body (or to a ring, collar or other structure which in turn is fixed to the catheter body).

Referring now to FIGS. **17***a* and **17***b*, a further embodiment of an angioplasty catheter **250** having an axially distensible attachment structure **258** is illustrated. External structure **252** is held over expandable dilatation balloon **254** and is fixed at one end to the distal end **260** of catheter body **256**. The external structure may comprise any structure typically used for removal of plaque/thrombus from a vessel wall such as a scoring structure, cutting structure or crushing structure. The proximal end **262** of external structure **252** is connected to the

distal end **264** of attachment structure **258**. The proximal end **266** of attachment structure **258** is fixed to the catheter body **256**. As described below, the attachment structure **258** may be configured to reduce forces applied on the external structure **252** and the catheter body **256** during expansion and contraction of balloon **254**.

In a preferred embodiment, attachment structure **258** comprises a cylindrical over-tube, or compliance tube, made of an elastic material. Over-tube **258** generally has an inner diameter that is slightly greater than the outer diameter of the catheter body **256**. Because only a small section of the proximal end of the attachment structure **258** is fixed to the catheter body, the distal end **264** attached to external structure **252** is free floating, and is free to slide axially and rotationally with respect to catheter body **256**. Attachment structure **252** may be fixed, for example by adhesion, directly to the to catheter body **256** and external structure **252**, or to a collar or other intermediate attachment means.

As balloon **254** is expanded, external structure **252** expands in circumference and contracts axially along the catheter body **256**, creating axial force A on attachment structure **258**. Attachment structure **258**, fixed to the catheter at its end **266**, axially stretches to accommodate the axial movement of the external structure **252**. External structure **252** also tends to rotate about the catheter body **256**, causing a torsional force T. The distal end **264** of attachment structure **258** rotates through the full range of motion of scoring structure **252** to accommodate torsional force T, while proximal end **266** remains stationary with respect to catheter body **256**.

The configuration illustrated in FIGS. **17***a* and **17***b* allows the compliance of the expandable system to be controlled. Generally, where one end of the scoring structure is free, the compliance of the expandable system will be a combination of the compliance of the balloon and the scoring structure. However, because the ends of the expandable system shown in FIG. **17** are fixed at distal end **260** and proximal end **266**, the attachment structure controls the compliance of the expandable system.

The compliance of the system may be varied by any combination of material selection, wall thickness, or length of the over-tube **258**. Over-tube **258** may comprise any elastomer, such as elastic polymer like Nylon, Pebax, or PET. Typically, compliance tube **258** is formed from extruded tubing, but it may also comprise braided polymeric or metallic fibers, or wire mesh. A high memory metal such as nitinol or stainless steel may also be used. Where the compliance tube comprises an extruded polymeric tube, the wall thickness can vary in the ranges set forth above, and the length of the tube can range from 1 cm to 10 cm. For the same material, the thinner-walled and longer the tube, the more compliant the system.

Referring to FIGS. **18***a-c*, the compliance of a angioplasty catheter **300** may also be varied by creating one or more perforations in compliance tube **258**. The perforations may comprise one or more slots in the circumference of the tubing. The slots may comprise one continuous slot spiraling across the length of compliance tube **258**, or may be a number of slots aligned in any number of patterns, such as helical **312**, or radial **314**. The slots may also be any number of shapes, such as circular or rectangular, and may have a discreet length or be contiguous across the surface of the compliance tube.

Referring to FIG. **19**, the outside diameter of compliance tube **258** may be tapered to facilitate delivery and retrieval of the scoring catheter **320** from the treatment site within the lumen. Generally, the outer diameter will be larger at the distal end **264** of the compliance tube **258** and smaller at the proximal end **266** of the compliance tube. The outside diameter D_1 at the distal end will vary depending on the profile of the scoring structure and balloon when collapsed but typically range from 0.004 in. to 0.01 in. larger than the outside diameter D_2 at the proximal end. The outside diameter D_2 at the proximal end is generally as close as possible to the outside diameter of the catheter body to create a smooth transition between the compliance tube and the catheter. As an example, for a catheter body having an outside diameter of 0.033 in., outside diameter D_1 at the distal end may be 0.042 in. with an inner diameter of 0.038 in., the inner diameter providing clearance between the catheter body so that the distal end of the compliance tube can move relative to the catheter body. Correspondingly, the outside diameter D_2 at the proximal end may taper down to 0.0345 in., with an inner diameter of 0.034 in. to closely match the catheter body having outside diameter with enough clearance to be bonded to the catheter body by an adhesive.

The taper may run across the whole length of the compliance tube, or alternatively be only tapered at a section of the length of the compliance tube. The tapered compliance tube **258** smoothes the transition between the scoring structure and catheter body, and minimizes the likelihood of the outer tube or scoring structure snagging or catching on a portion of the luminal wall during delivery or retrieval of the catheter.

Now referring to FIG. **20**, an alternative embodiment of a scoring catheter **350** is shown having a manipulator **360**. The attachment structure **258** is connected at its distal end **264** to the scoring structure **252**. Instead of being secured directly to the catheter body **256**, the proximal end **266** is attached to manipulator **360**. Typically, the manipulator **360** is positioned at the proximal end of the catheter body **256** and the attachment structure **258** extends from the scoring structure across the length of the catheter body. Like the above embodiments, the attachment structure is capable of axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In some embodiments, the compliance of the scoring structure **252** and balloon **254** is controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. In one aspect, the attachment structure **258** may be axially advanced with respect to the catheter body **256** as the balloon is being inflated or deflated. For example, the attachment structure **258** may be pulled away from the distal end of the catheter body **256** while the balloon **254** is being expanded to constrain the compliance of balloon. The attachment structure **258** may also be pulled away from the distal end of the catheter body **256** during or after the balloon **254** is being deflated to minimize the profile of the balloon and scoring structure. Alternatively, the manipulator **360** may be used to rotate the attachment structure **258** with respect to the catheter body **256** to control the compliance of the balloon and scoring structure during transition from a collapsed to expanded state and back to a collapsed state.

Now referring to FIGS. **21** and **22**, a scoring cage structure **400** is illustrated having a two-layer laminated compliance tube **402**. As shown in FIG. **22**, the compliance tube **402** has a laminated structure **404** at least its distal end **410**. The laminated structure holds the proximal ends **408** of the scoring elements **406** as shown in broken line in FIG. **22**. The scoring elements **406** may be sized to fit over the outside of the compliance tube **402**, as illustrated in FIG. **22**, with the lamination covering the elements. Alternatively, the compliance sleeve tube **402** may be sized to fit inside of the scoring structure **406**, with the laminating layer(s) formed over the elements **406** (not shown).

The laminating structure may be composed of a polymer similar to the compliance tube **402**, and may be heat shrunk or melted to thermally bond the compliance sleeve to the com-

pliance tube and sandwich the scoring structure **406**. Alternatively, an adhesive or other bonding method such as ultrasonic or RF energy may be used to laminate the structure. The laminated structure as shown in FIGS. **21** and **22**, provides a smoothed transition and strengthened bond between the scoring cage and the attachment structure. Such a smooth transition is a particular advantage when withdrawing the scoring cage from the vasculature.

FIGS. **23** and **24** illustrate scoring cage **400** positioned over an expandable dilation balloon **412**. As shown in FIG. **24**, distal end **418**, of the scoring structure may be coupled to the distal tip **414** of the catheter body by an end cap **416**. The end cap **416** may be composed of a compatible polymer and thermally bonded with the catheter body to fix distal end **418** of the scoring structure to the catheter body.

Now referring to FIGS. **25-27**, a method is illustrated for mounting an expandable scoring cage **406** over a balloon catheter. The scoring cage **406** is pre-expanded by loading it over an insertion tube **422** that has an inner diameter slightly larger than the outer diameter of the balloon **412**. A catheter body **420** having a balloon **412** is then inserted into the inner diameter of the insertion tube **422** and advanced until the balloon **412** is appropriately positioned with respect to the scoring structure **406**, as illustrated in FIG. **26**. The insertion tube **422** is then pulled back to allow the expanded scoring structure to collapse over the balloon **412** and the catheter body **420**, as shown in FIG. **27**. The scoring structure **406** may then be secured at its distal end **418** to the distal tip **414** of the catheter body **420** and the proximal end **424** of the scoring structure/attachment structure assembly to a medial location on the catheter body **420**.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Alternate embodiments are contemplated that fall within the scope of the invention.

What is claimed is:

1. An angioplasty catheter comprising: a catheter body having a proximal end and a distal end; a radially expandable shell near the distal end of the catheter body;

an external structure carried over but unattached to the shell, wherein the external structure has a distal end fixedly attached to the catheter body at a location distal to the radially expansible shell so that a proximal end of the external structure is drawn distally axially and/or rotates relative to the catheter body as the shell is radially expanded; and

an attachment structure having a proximal end fixedly attached to the catheter body and a distal end attached to the proximal end of the external structure, wherein the attachment structure comprises a tubular body having one or more perforations to enhance compliance.

2. The catheter as in claim **1**, wherein the external structure comprises a scoring structure.

3. The catheter as in claim **1**, wherein the external structure comprises a cutting structure.

4. The catheter as in claim **1**, wherein at least a portion of the external structure is arranged helically over the shell.

5. The catheter as in claim **1**, wherein the tubular body is formed from a metal.

6. The catheter as in claim **1**, wherein the tubular body is formed from a polymer.

7. The catheter as in claim **1**, wherein the perforations in the tubular body comprise slots.

8. The catheter as in claim **7**, wherein the slot is formed as a continuous spiral.

9. The catheter as in claim **7**, wherein the one or more perforations comprise one or more slots extending along the outside circumference of the compliance tube.

10. The catheter as in claim **7**, wherein the slots form a pattern along the outside circumference of the compliance tube.

11. The catheter as in claim **7**, wherein the slots are parallel to each other.

12. The catheter as in claim **7**, wherein the slots extend helically across the compliance tube.

13. The catheter as in claim **7**, wherein the slots extend radially across the compliance tube.

14. The catheter as in claim **13**, wherein the slots extend helically across the compliance tube.

15. The catheter as in claim **13**, wherein the slots extend radially across the compliance tube.

16. The catheter as in claim **13**, wherein the slots are circular in shape.

17. The catheter as in claim **13**, wherein the slots are rectangular in shape.

18. The catheter as in claim **7**, wherein the slots are circular in shape.

19. The catheter as in claim **7**, wherein the slots are rectangular in shape.

* * * * *

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(12) **United States Patent**
Konstantino et al.

(10) **Patent No.: US 8,721,667 B2**
(45) **Date of Patent: *May 13, 2014**

(54) **APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/841,755**

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Related U.S. Application Data

(60) Division of application No. 13/292,716, filed on Nov. 9, 2011, now Pat. No. 8,454,636, which is a continuation of application No. 10/917,917, filed on Aug. 13, 2004, now Pat. No. 8,080,026, which is a continuation-in-part of application No. 10/810,330, filed on Mar. 25, 2004, now Pat. No. 7,955,350, which is a continuation-in-part of application No. 10/631,499, filed on Jul. 30, 2003, now Pat. No. 7,686,824.

(60) Provisional application No. 60/442,161, filed on Jan. 21, 2003.

(51) **Int. Cl.**
A61B 17/22 (2006.01)

(52) **U.S. Cl.**
USPC **606/159**; 623/1.11

(58) **Field of Classification Search**
USPC 606/159, 194, 108, 192, 198; 604/22, 604/500, 96.01, 101; 623/1.11
See application file for complete search history.

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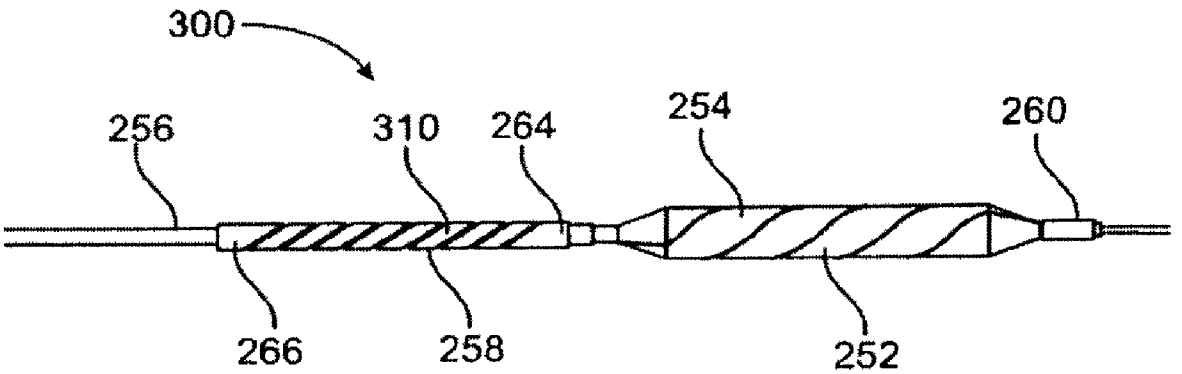
Primary Examiner — Victor Nguyen
(74) *Attorney, Agent, or Firm* — James W. Geriak; Sheppard Mullin Richter & Hampton LLP

(57) **ABSTRACT**

An angioplasty catheter includes a catheter body having a balloon or other radially expandable shell at its distal end. A non-axial external structure is carried over the shell and scores a stenosed region in a blood vessel when the balloon is inflated therein. The catheter has an attachment structure disposed between the catheter body and the balloon to accommodate foreshortening and rotation of the external structure as the balloon is expanded. The external structure may be part of a helical cage structure which floats over the balloon.

10 Claims, 15 Drawing Sheets



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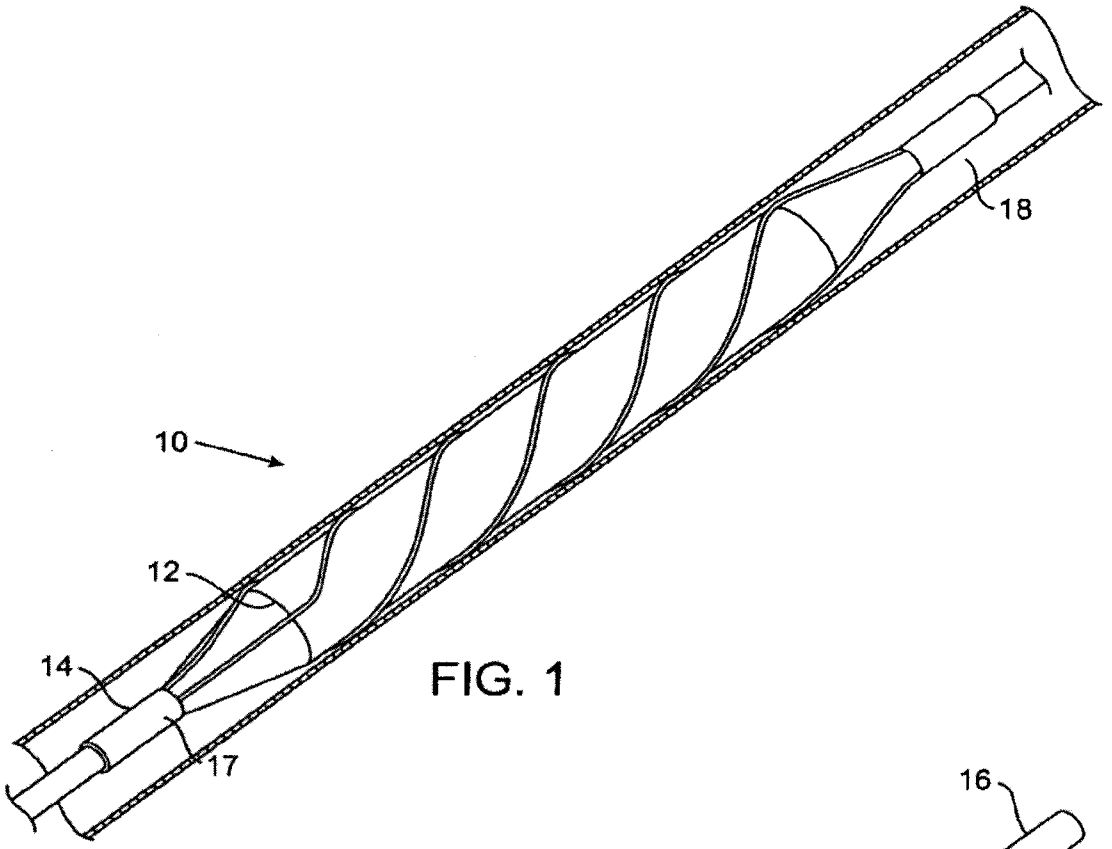


FIG. 1

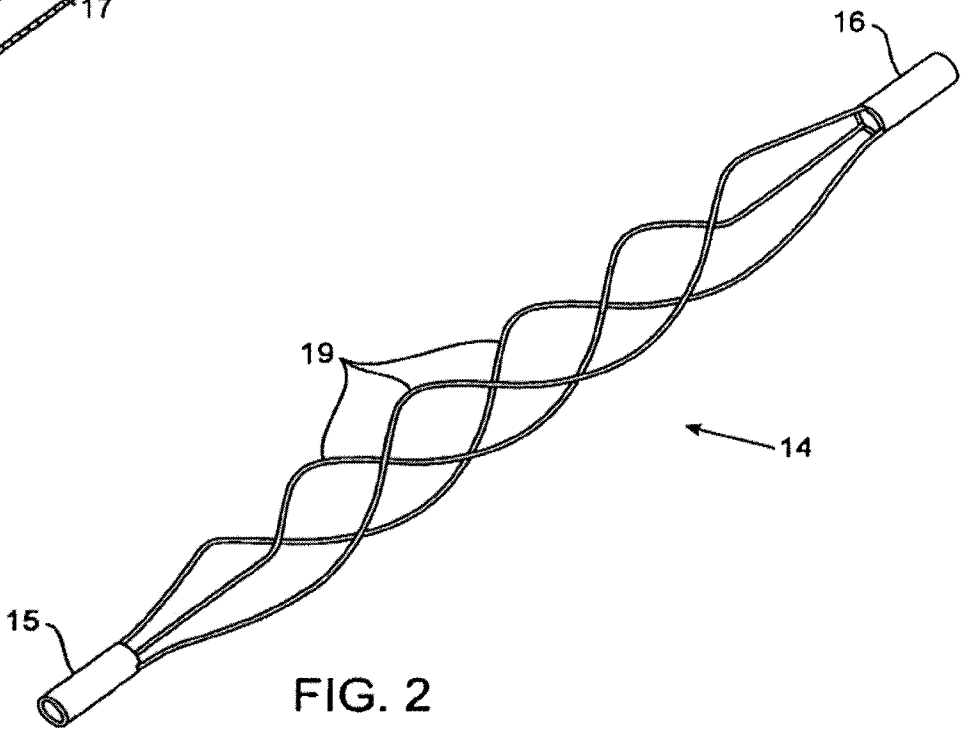


FIG. 2

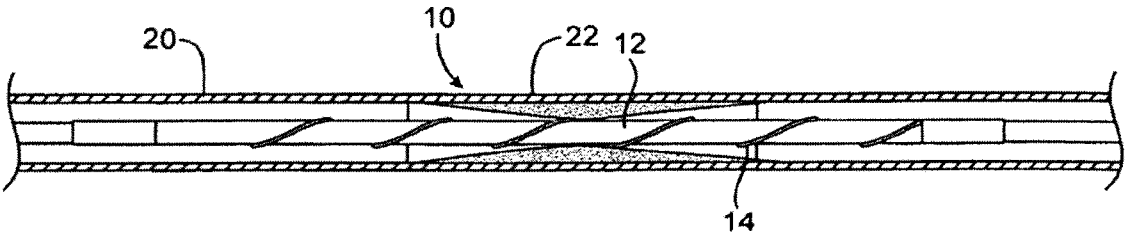


FIG. 1A

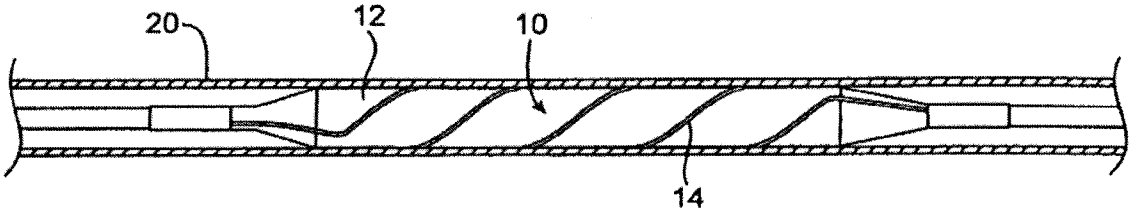
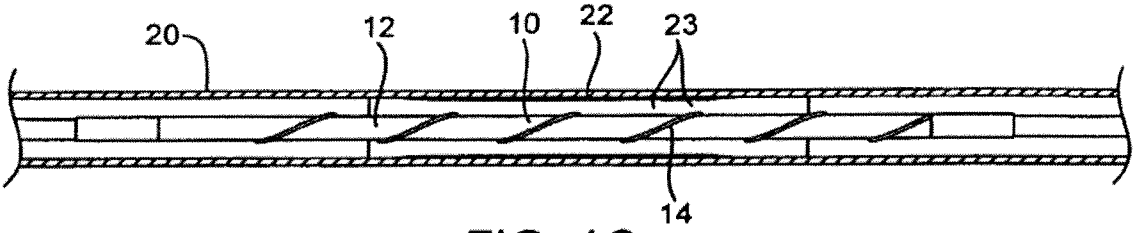


FIG. 1B



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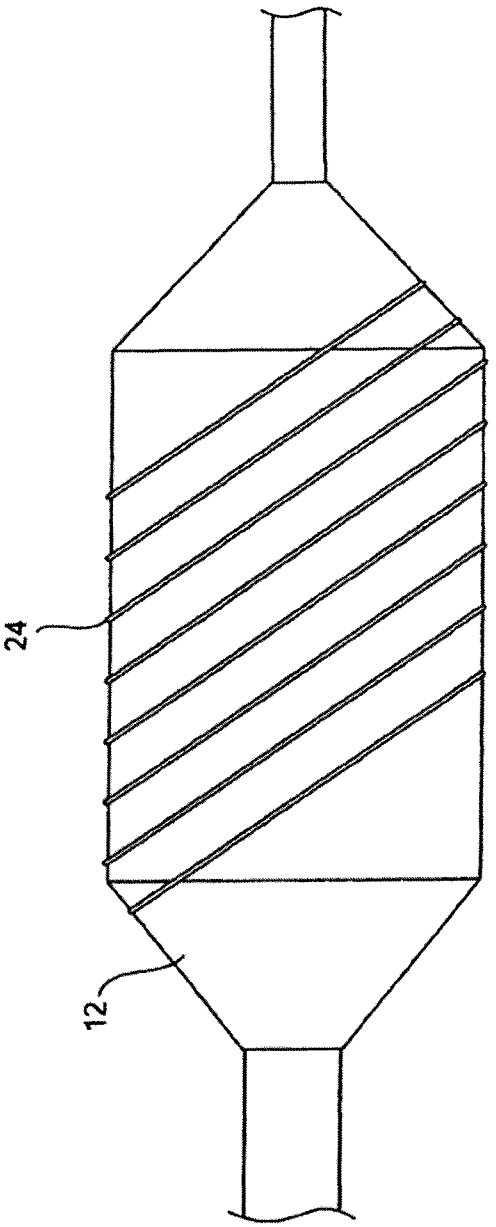
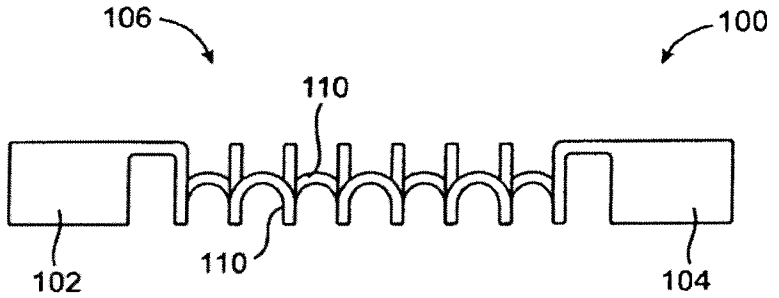


FIG. 3



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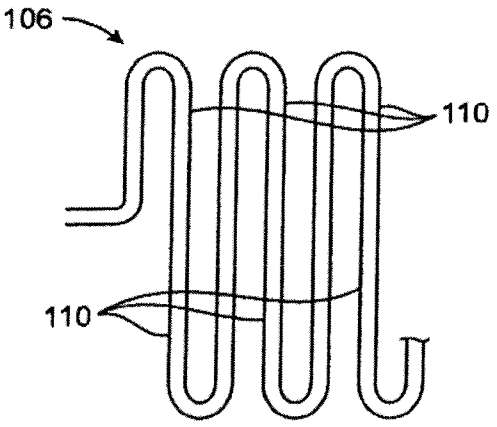
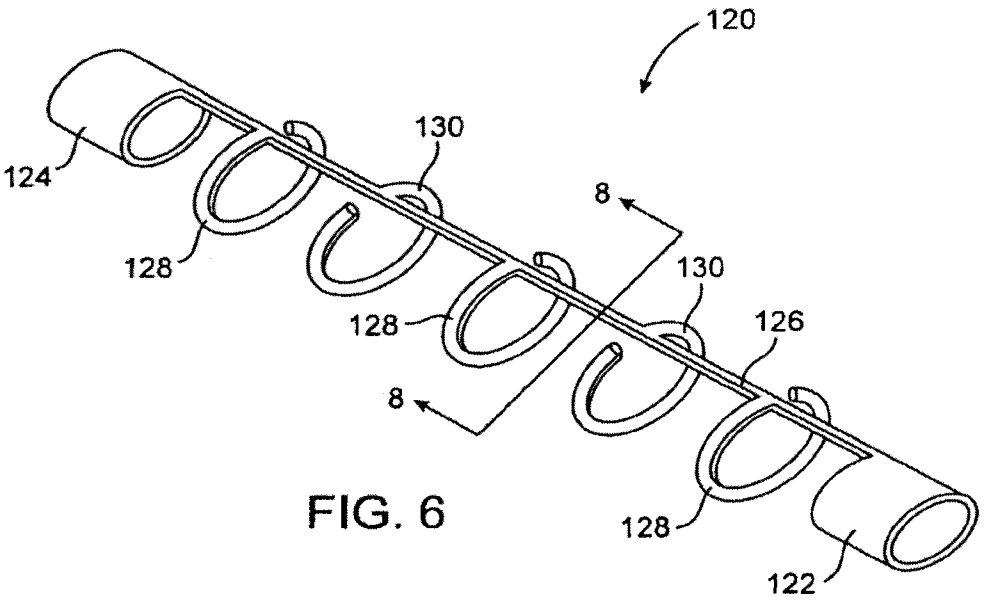


FIG. 5



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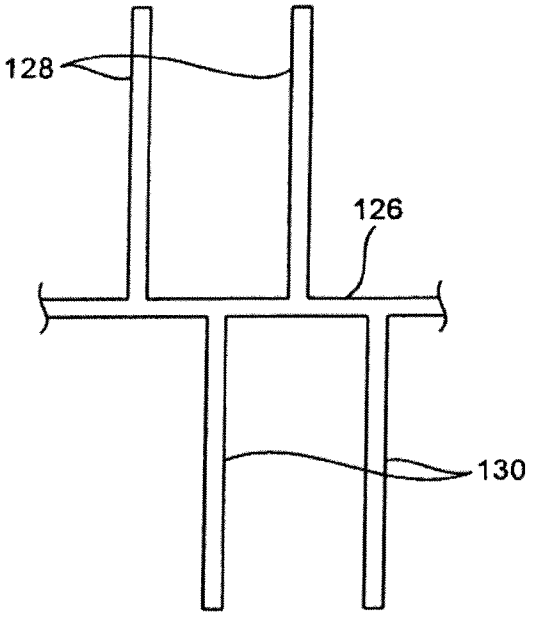

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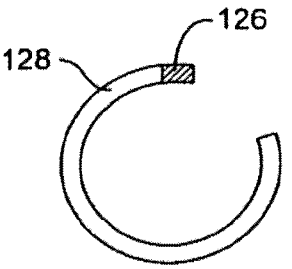

FIG. 8

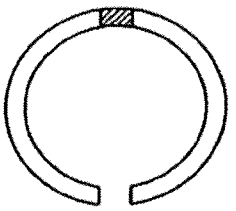

FIG. 9

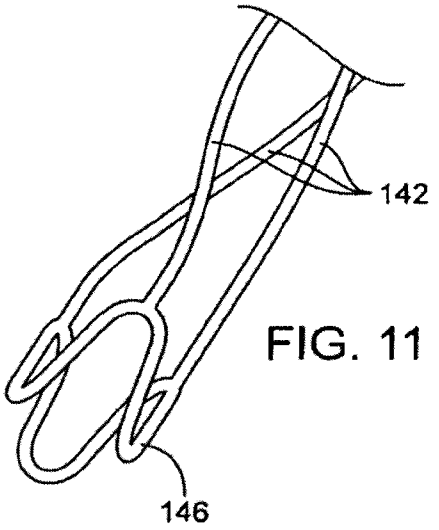

FIG. 11

FIG. 10

FIG. 12

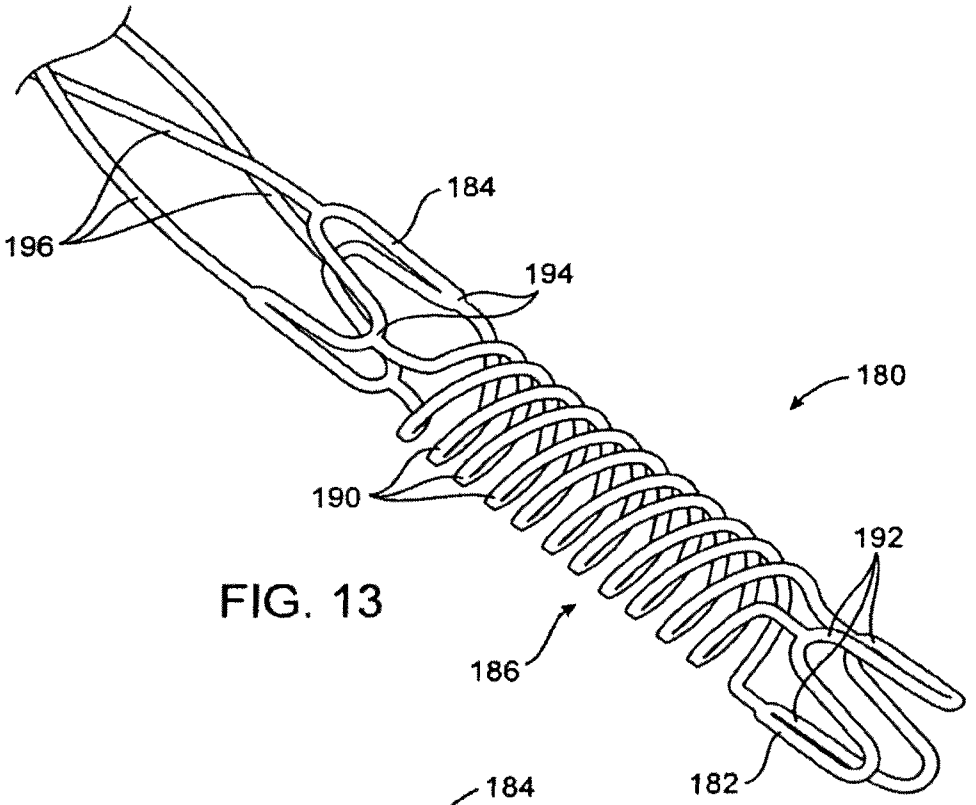

FIG. 13

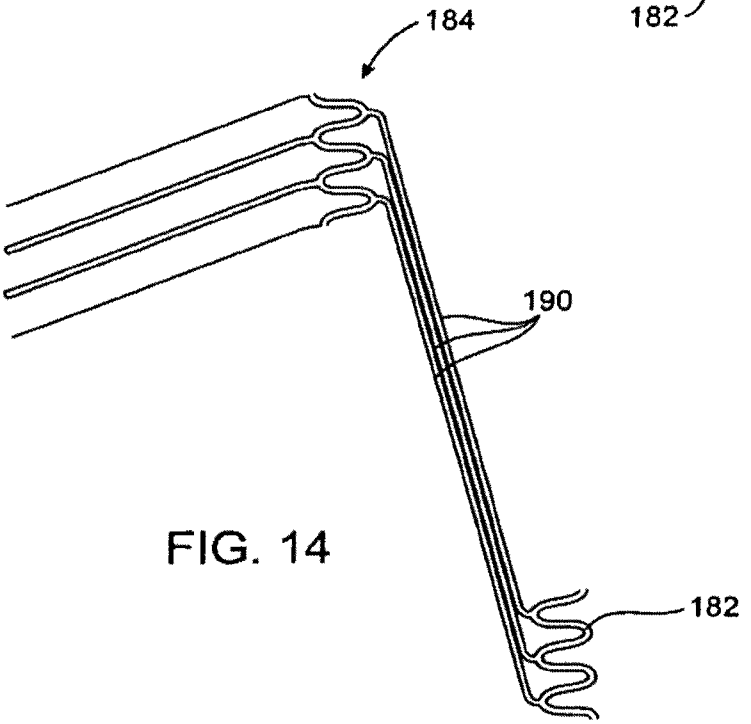

FIG. 14

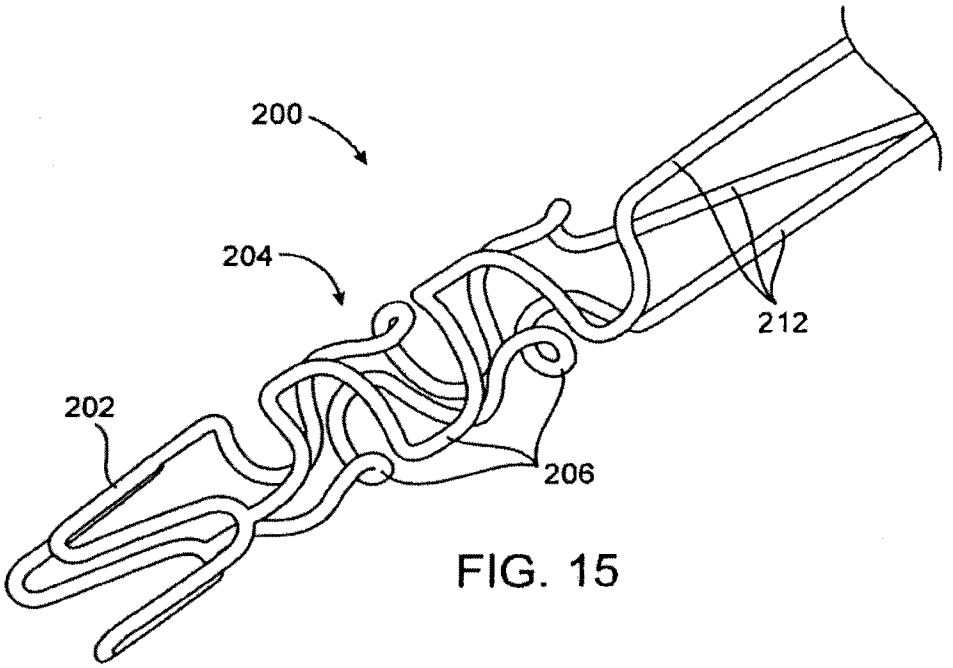

FIG. 15

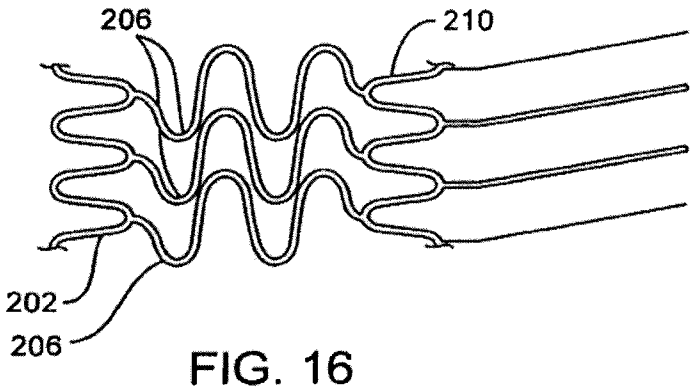

FIG. 16

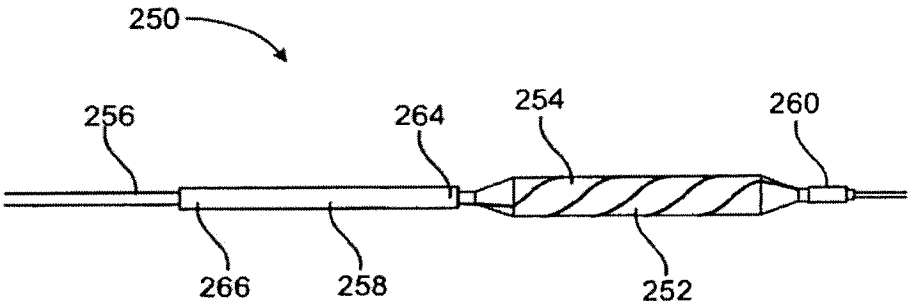

FIG. 17A

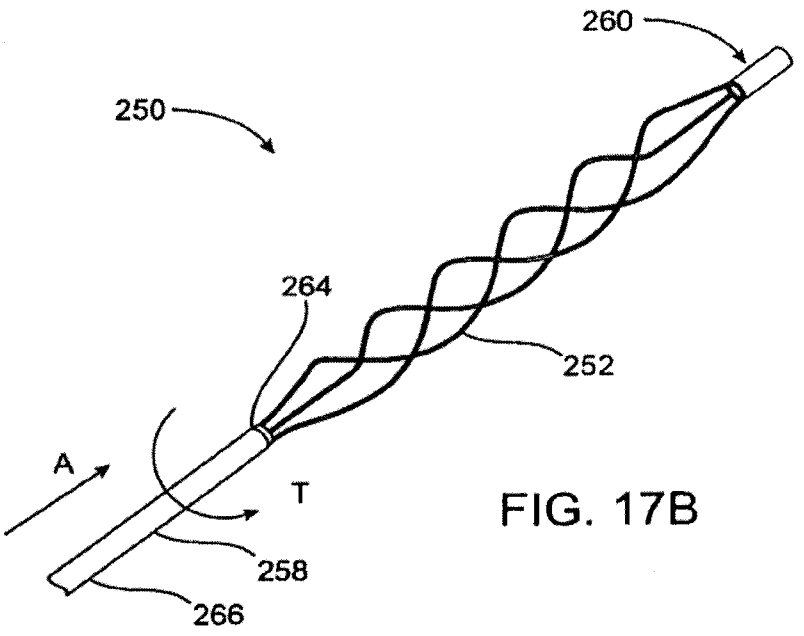

FIG. 17B

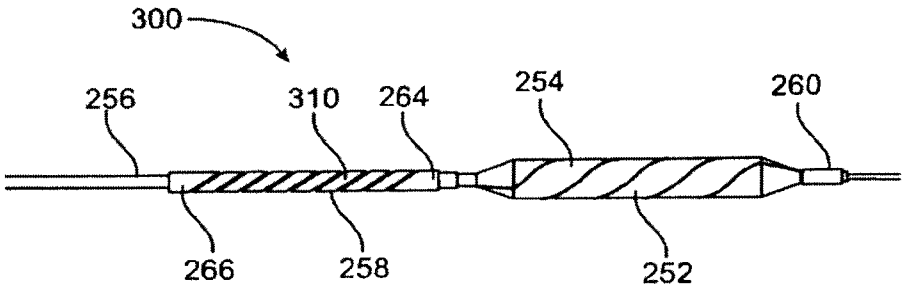

FIG. 18A

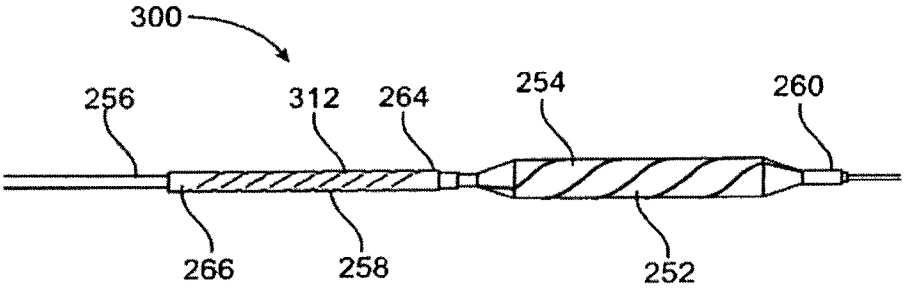

FIG. 18B

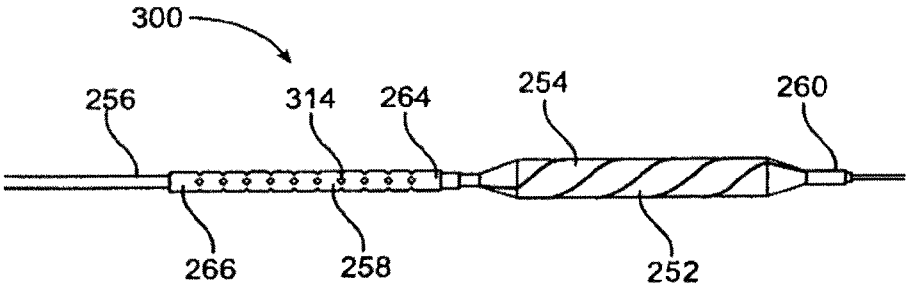

FIG. 18C

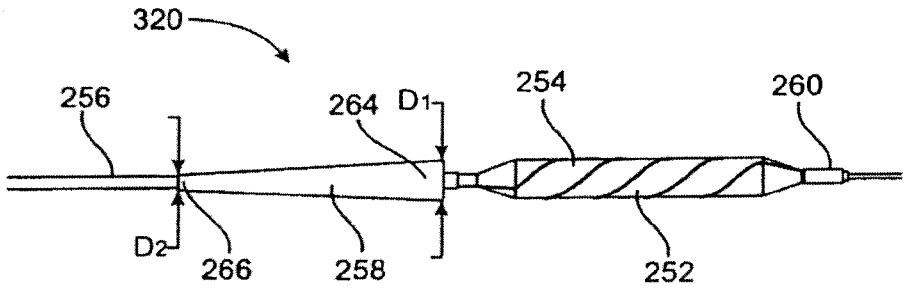
320
256
264
D1
254
260
D2
266
258
252

FIG. 19

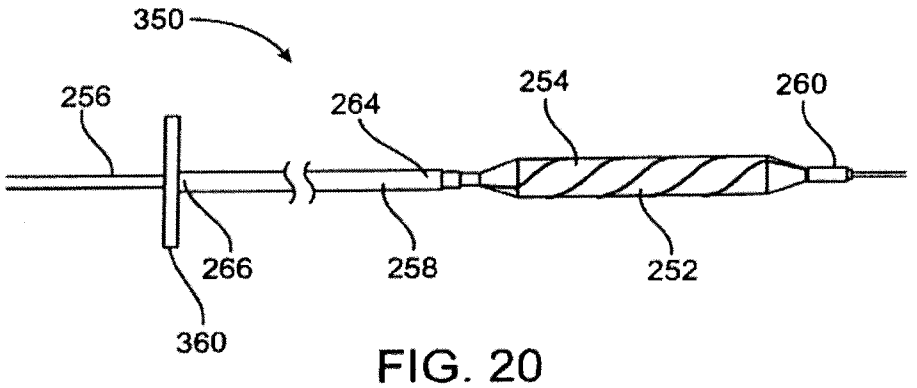
350
256
264
254
260
266
258
252
360

FIG. 20

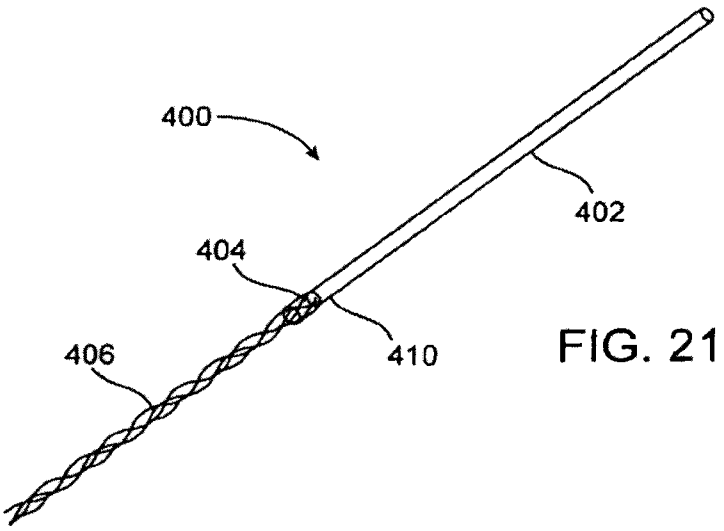

FIG. 21

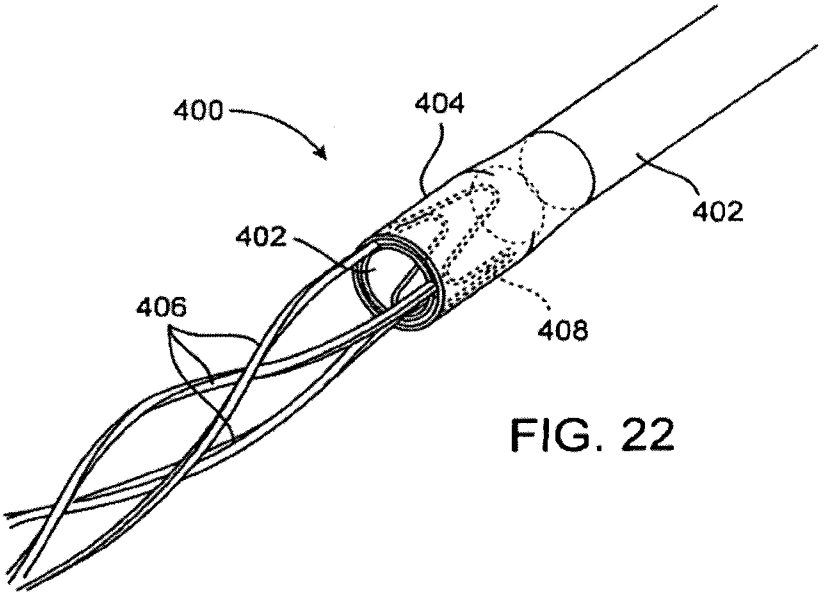

FIG. 22

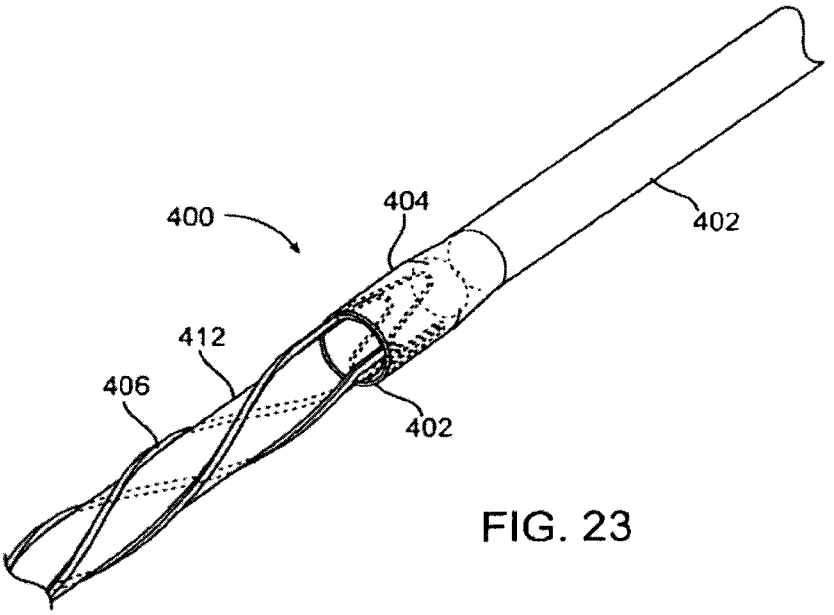

FIG. 23

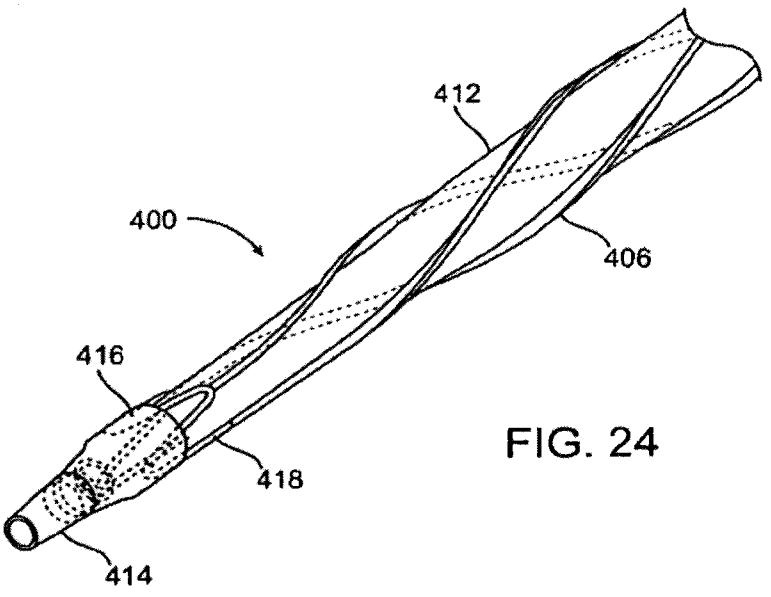

FIG. 24

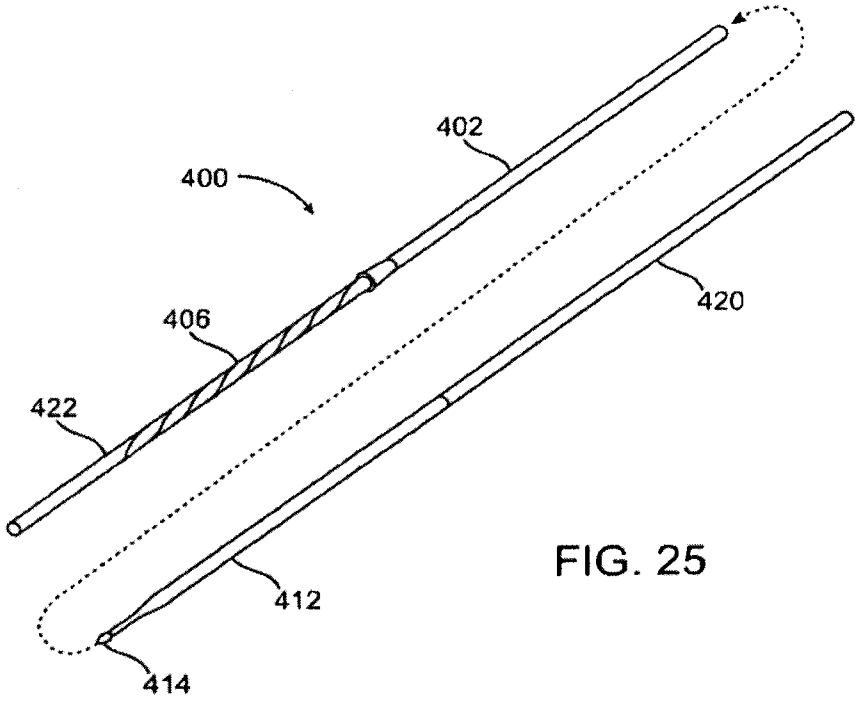

FIG. 25

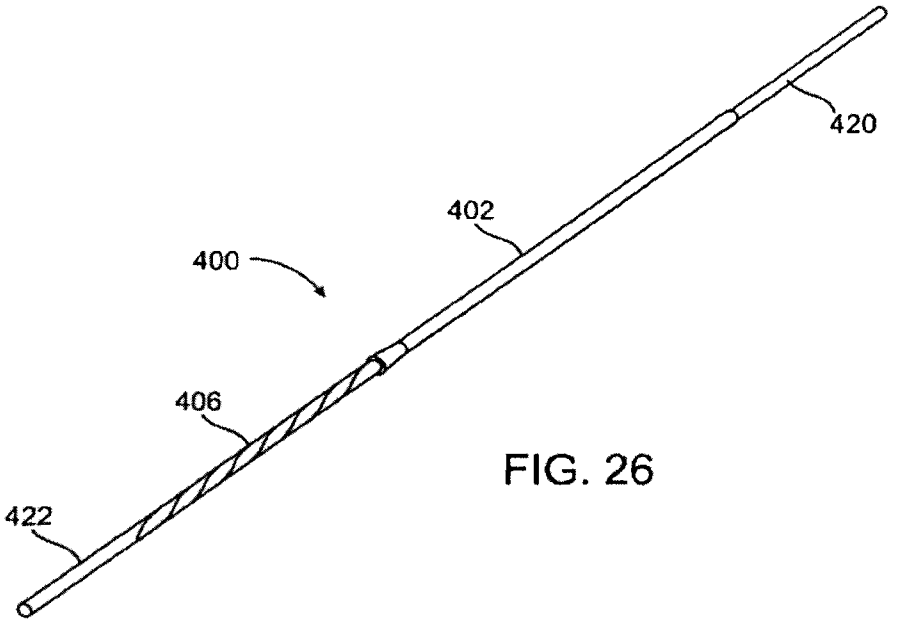

FIG. 26

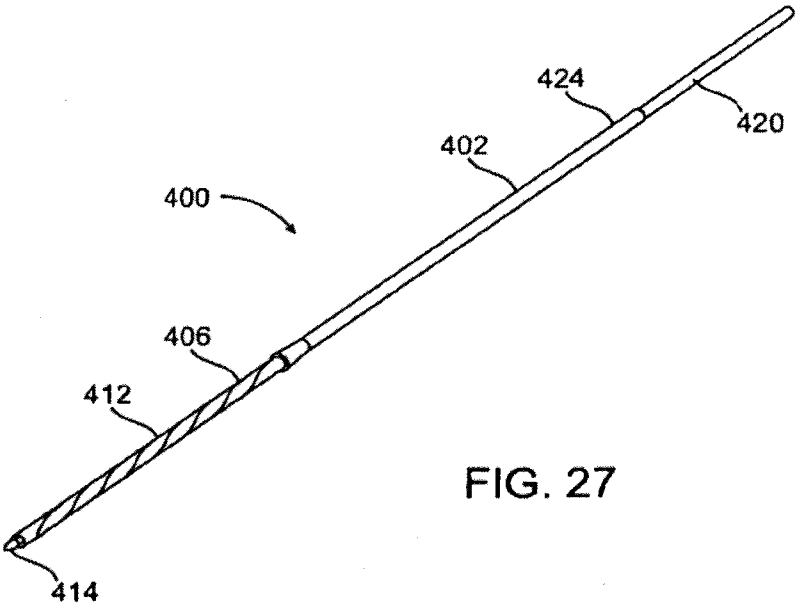

FIG. 27

APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a divisional of co-pending U.S. patent application Ser. No. 13/292,716, filed on Nov. 9, 2011, which is a continuation of U.S. patent application Ser. No. 10/917,917, filed on Aug. 13, 2004, now U.S. Pat. No. 8,080,026 issued on Dec. 20, 2011, which is a continuation-in-part of commonly assigned U.S. patent application Ser. No. 10/810,330, filed on Mar. 25, 2004, now U.S. Pat. No. 7,955,350 issued on May 18, 2011, which is a continuation-in-part of U.S. patent application Ser. No. 10/631,499, filed on Jul. 30, 2003, now U.S. Pat. No. 7,686,824, issued on Mar. 30, 2010, which claims the benefit under 35 USC §119(e) of U.S. Provisional Application No. 60/442,161, filed on Jan. 21, 2003, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the field of medical devices, more specifically to medical devices intended to treat stenoses in the vascular system.

Balloon dilatation (angioplasty) is a common medical procedure mainly directed at revascularization of stenotic vessels by inserting a catheter having a dilatation balloon through the vascular system. The balloon is inflated inside a stenosed region in a blood vessel in order to apply radial pressure to the inner wall of the vessel and widen the stenosed region to enable better blood flow.

In many cases, the balloon dilatation procedure is immediately followed by a stenting procedure where a stent is placed to maintain vessel patency following the angioplasty. Failure of the angioplasty balloon to properly widen the stenotic vessel, however, may result in improper positioning of the stent in the blood vessel. If a drug-eluting stent is used, its effectiveness may be impaired by such improper positioning and the resulting restenosis rate may be higher. This is a result of several factors, including the presence of gaps between the stent and the vessel wall, calcified areas that were not treated properly by the balloon, and others.

Conventional balloon angioplasty suffers from a number of other shortcomings as well. In some cases the balloon dilatation procedure causes damage to the blood vessel due to aggressive balloon inflation that may stretch the diseased vessel beyond its elastic limits. Such over inflation may damage the vessel wall and lead to restenosis of the section that was stretched by the balloon. In other cases, slippage of the balloon during the dilatation procedure may occur. This may result in injury to the vessel wall surrounding the treated lesion. One procedure in which slippage is likely to happen is during treatment of in-stent restenosis, which at present is difficult to treat by angioplasty balloons. Fibrotic lesions are also hard to treat with conventional balloons, and elastic recoil is usually observed after treatment of these lesions. Many long lesions have fibrotic sections that are difficult to treat using angioplasty balloons.

An additional problem associated with balloon angioplasty treatment has been the "watermelon seed effect." Angioplasty is carried out at very high pressures, typically up to twenty atmospheres or higher, and the radially outward pressure of the balloon can cause axial displacement of the balloon in a manner similar to squeezing a watermelon seed with the fingers. Such axial displacement, of course, reduces the effectiveness of balloon dilatation. Another problem with conventional angioplasty balloon design has been deflation of the balloon. Even after the inflation medium is removed from a balloon, the deflated configuration will have a width greater than the original folded configuration which was introduced to the vasculature. Such an increase in profile can make removal of the balloon difficult.

Atherectomy/Thrombectomy devices intended to remove plaque/thrombus material may also include a structure that expands in a lesion while the plaque/thrombus removal mechanism is within this structure. The removed material is either being stacked in the catheter or sucked out thru the catheter. When the procedure is done, the expandable structure is collapsed and the catheter removed. Foreign object removal devices usually include a basket structure that needs to be expanded to collect the object and then collapse for retrieval. Distal protection devices usually include a basket structure that support a mesh that needs to be expanded distal to the treated lesion to collect the loose objects and then collapse for retrieval.

These devices usually include an elastic metallic material that needs to be expanded in the vascular system to fulfill its task and afterwards collapse to a small diameter to facilitate retrieval. The transition between the collapsed (closed) configuration to the expanded (open) configuration can be done in two ways: the structure can be at a normally closed (collapsed) configuration in which force is applied to cause the structure to expand. In this case, the elastic recoil of the structure will cause it to collapse back to closed configuration when the expanding force ceases. The structure may also be at a normally open (expanded) configuration in which a constraining element is forced over it to hold it down for the collapsed configuration (for example a constraining tube). When this constraining element is removed the structure is free to expand to the expanded (open) configuration. The structure material may also be non elastic. In this case, the structure will need to be forced to transit between both collapsed and expanded configurations.

One problem associated with conventional angioplasty expansion systems is that the transition between the collapsed and expanded configurations involves significant rotational and axial reaction forces. These reaction forces are applied by the structure on the catheter as a result of the force applied by the catheter to expand or close the structure. Axial reaction forces are created due the foreshortening of the structure during expansion. Rotational reaction forces (torques) are created when a non longitudinal element is forced to expand/collapse. Since the catheters are usually less stiff than the structure, these reaction forces may cause the structure to not expand or collapse properly, or cause undesired deformation to the catheter itself.

To overcome at least some of these problems, U.S. Pat. No. 5,320,634 describes the addition of cutting blades to the balloon. The blades can cut the lesions as the balloon is inflated. U.S. Pat. No. 5,616,149 describes a similar method of attaching sharp cutting edges to the balloon. U.S. Patent Publication 2003/0032973 describes a stent-like structure having non-axial grips for securing an angioplasty balloon during inflation. U.S. Pat. No. 6,129,706 describes a balloon catheter having bumps on its outer surface. U.S. Pat. No. 6,394,995 describes a method of reducing the balloon profile to allow crossing of tight lesions. U.S. Patent Publication 2003/0153870 describes a balloon angioplasty catheter having a flexible elongate elements that create longitudinal channels in a lesion or stenosis.

While the use of angioplasty balloons having cutting blades has proved to be a significant advantage under many circumstances, the present cutting balloon designs and methods for their use continue to suffer from shortcomings. Most commercial cutting balloon designs, including those available from INTERVENTIONAL TECHNOLOGIES, INC., of San Diego, Calif. now owned by BOSTON SCIENTIFIC, of Natick, Mass., have relatively long, axially aligned blades carried on the outer surface of an angioplasty balloon. Typically, the blades are carried on a relatively rigid base directly attached to the outer balloon surface. The addition of such rigid, elongated blade structures makes the balloon itself quite stiff and limits the ability to introduce the balloon through torturous regions of the vasculature, particularly the smaller vessels within the coronary vasculature. Moreover, the cutting balloons can be difficult to deflate and collapse, making removal of the balloons from the vasculature more difficult than with corresponding angioplasty balloons which do not include cutting blades. Additionally, the axially oriented cuts imparted by such conventional cutting balloons do not always provide the improved dilatation and treatment of fibrotic lesions which would be desired.

For these reasons, it would be desirable to provide improved cutting balloon designs and methods for their use. In particular, it would be desirable to provide cutting balloons which are highly flexible over the length of the balloon structure, which readily permit deflation and facilitate removal from the vasculature, and which are effective in treating all forms of vascular stenoses, including but not limited to treatment of highly calcified plaque regions of diseased arteries, treatment of small vessels and/or vessel bifurcations that will not be stented, treatment of ostial lesions, and treatment of in-stent restenosis (ISR). Moreover, it would be desirable if such balloon structures and methods for their use could provide for improved anchoring of the balloon during dilatation of the stenosed region.

It would further be desirable to minimize the reaction forces applied by the external structure to the catheter, and at the same time be able to control the expansion of the expandable structure. It would also be desirable to adjust the compliance of the system in a predictable way without changing the materials or geometry of the expandable structure. At least some of these objectives will be met with the inventions described hereinafter.

2. Description of the Background Art

The following U.S. patents and printed publication relate to cutting balloons and balloon structures: U.S. Pat. Nos. 6,450,988; 6,425,882; 6,394,995; 6,355,013; 6,245,040; 6,210,392; 6,190,356; 6,129,706; 6,123,718; 5,891,090; 5,797,935; 5,779,698; 5,735,816; 5,624,433; 5,616,149; 5,545,132; 5,470,314; 5,320,634; 5,221,261; 5,196,024; and Published U.S. Patent Application 2003/0032973. Other U.S. patents of interest include U.S. Pat. Nos. 6,454,775; 5,100,423; 4,998,539; 4,969,458; and 4,921,984.

SUMMARY OF THE INVENTION

The present invention provides improved apparatus and methods for the dilatation of stenosed regions in the vasculature. The stenosed regions will often include areas of fibrotic, calcified, or otherwise hardened plaque or other stenotic material of the type which can be difficult to dilatate using conventional angioplasty balloons. The methods and apparatus will often find their greatest use in treatment of the arterial vasculature, including but not limited to the coronary arterial vasculature, but may also find use in treatment of the venous and/or peripheral vasculature, treatment of small vessels and/or vessel bifurcations that will not be stented, treatment of ostial lesions, and treatment of ISR.

In a first aspect of the present invention, a scoring catheter comprises a catheter body having a proximal end and a distal end, a radially expandable shell (typically an angioplasty balloon) near the distal end of the catheter body, and a non-axial scoring structure carried over the shell. By "non-axial scoring structure," it is meant that the structure will be able to score or cut stenotic material within a treated blood vessel along lines which are generally in a non-axial direction. For example, the scoring lines may be helical, serpentine, zig-zag, or may combine some axial components together with such non-axial components. Usually, the non-axial scoring pattern which is imparted will include scoring segments which, when taken in total, circumscribe at least a majority of and usually the entire inside wall of the blood vessel up to one time, preferably more than one time, usually more than two times, often at least three times, more often at least four, five, six, or more times. It is believed that the resulting scoring patterns which circumscribe the inner wall of the vessel will provide improved results during subsequent balloon dilatation.

Usually the scoring structure will comprise at least one continuous, i.e., non-broken, scoring element having a length of at least 0.5 cm, more usually at least 1 cm, often at least 2 cm, usually at least 3 cm, and sometimes at least 4 cm or more. Alternatively, the scoring structure may comprise a plurality of much smaller segments which may be arranged in a helical or other pattern over the balloon, typically having a length in the range from 0.1 cm to 2 cm, often being 0.5 cm or less, sometimes being 0.3 cm or less.

In order to promote scoring of the blood vessel wall when the underlying expandable shell is expanded, the scoring structure will usually have a vessel contact area which is 20% or less of the area of the expandable shell, usually being below 10%, and often being in the range from 1% to 5% of the area of the expandable shell. The use of a shell having such a relatively small contact area increases the amount of force applied to the vascular wall through the structure by expansion of the underlying expandable shell. The scoring structure can have a variety of particular configurations, often being in the form of a wire or slotted tube having a circular, square, or other cross-sectional geometry. Preferably, the components of the scoring structure will comprise a scoring edge, either in the form of a honed blade, a square shoulder, or the like. A presently preferred scoring edge is electropolished and relatively small.

In a preferred embodiment, the scoring structure may be formed as a separate expandable cage which is positioned over the expandable shell of the catheter. The cage will usually have a collar or other attachment structure at each end for placement on the catheter body on either side of the expandable shell. A collar may be a simple tube, and other attachment structures will usually be crimpable or otherwise mechanically attachable to the catheter body, such as a serpentine or other ring structure. The attachment structures on the cage may be attached at both ends to the catheter body, but will more usually be attached at only a single end with the other end being allowed to float freely. Such freedom allows the scoring structure to shorten as the structure is expanded on the expandable shell. In certain embodiments, both ends of the scoring structure will be fixed to the catheter body, but at least one of the attachment structures will have a spring or other compliant attachment component which provides an axial extension as the center of the scoring structure foreshortens.

In many cases, since the scoring elements are non-axial, there are torques induced during the expansion of the balloon and the shortening of the scoring structure. These torques may be high, and if one end of the scoring structure is constrained from rotation, the scoring element will not expand properly. The final expanded configuration of the scoring element is achieved via shortening and rotation.

In a preferred embodiment, both sides of the scoring element are fixed to the catheter, but at least one side will have a compliant structure which will provide axial tension and at the same time will allow the scoring element to rotate to its final configuration.

In some cases both ends of the scoring element are fixed and the shortening is achieved by deformation of the wire. For example, the wire can have a secondary structure which permits elongation (e.g., it may be a coiled filament) or can be formed from a material which permits elongation, e.g., nitinol. The scoring element can be attached in both ends, in a way that will allow rotation. In the case were the torques are low (depending on the design of the scoring element) there is no need for rotation and the torque can be absorbed either be the scoring element or by the catheter.

In all cases, the scoring structure is preferably composed of an elastic material, more preferably a super elastic material, such as nitinol. The scoring structure is thus elastically expanded over the expandable shell, typically an inflatable balloon similar to a conventional angioplasty balloon. Upon deflation, the scoring structure will elastically close to its original non-expanded configuration, thus helping to close and contain the balloon or other expandable shell.

In some cases the scoring element will be a combination of more than one material. In one case the scoring element can be made from nitinol and parts of it can be made from stainless steel. In other cases the scoring element can be made of stainless steel or nitinol and part of it can be made from polymer to allow high deformations.

In other preferred embodiments, the assembly of the shell and the scoring structure will be sufficiently flexible to permit passage through tortuous regions of the vasculature, e.g., being capable of bending at radius of 10 mm or below when advanced through 45°, 90°, or higher bends in the coronary vasculature. Usually, the scoring structure will comprise one or more scoring elements, wherein less than 70% of the cumulative length of the scoring element is aligned axially on the shell when expanded, preferably being less than 50% of the cumulative length, and more preferably being less than 25% of the cumulative length. In other instances, the scoring structure may comprise one or more scoring elements, wherein the cumulative length of the scoring element includes a non-axial component of at least 10 mm, preferably at least 12 mm, and more preferably 36 mm. Preferably, at least some of the scoring elements will have scoring edges which are oriented radially outwardly along at least a major portion of their lengths at all times during inflation and deflation and while inflated. By "radially outward," it is meant that a sharp edge or shoulder of the element will be oriented to score or cut into the stenotic material or the interior wall of the treated vessel, particularly as the shell is being inflated.

The scoring elements will usually, but not necessarily, have a scoring edge formed over at least a portion of their lengths. A "scoring edge" may comprise a sharpened or honed region, like a knife blade, or a square shoulder as in scissors or other shearing elements. Alternatively, the scoring elements may be free from defined scoring edges, e.g., having circular or the other non-cutting profiles. Such circular scoring elements will concentrate the radially outward force of the balloon to cause scoring or other disruption of the plaque or other stenotic material being treated.

In a second aspect of the present invention, the scoring catheter comprises a catheter body and a radially expandable shell, generally as set forth above. The scoring structure will be composed of elements which circumscribe the radially expandable shell. By "circumscribing the radially expandable shell," it is meant that at least some scoring elements of the scoring structure will form a continuous peripheral path about the exterior of the expandable shell during expansion. An example of such a fully circumscribing structure is a helical structure which completes up to one 360° path about the balloon before, during, and after expansion, usually completing two complete revolutions, and frequently completing three, four, or more complete revolutions. Exemplary helical structures may include two, three, four, or more separate elements, each of which is helically arranged around the radially expandable shell.

In a third aspect of the present invention, a scoring catheter comprises a catheter body and a radially expandable shell, generally as set forth above. An elongated scoring structure is carried over the shell, and the assembly of the shell and the scoring structure will be highly flexible to facilitate introduction over a guide wire, preferably being sufficiently flexible when unexpanded so that it can be bent at an angle of at least 90°, preferably 180°, at a radius of 1 cm without kinking or otherwise being damaged. Such flexibility can be determined, for example, by providing a solid cylinder having a radius of 1 cm and conforming the assembly of the scoring structure and expandable shell over the cylinder. Alternatively, the assembly can be advanced over a guide wire or similar element having a 180° one centimeter radius bend. In either case, if the assembly bends without kinking or other damage, it meets the requirement described above. Other specific features in this further embodiment of the catheters of the present invention are as described above in connection with the prior embodiments.

In a fourth aspect of the present invention, a plaque scoring catheter comprises a catheter body and a radially expandable balloon, generally as set forth above. A plurality of scoring elements are distributed over the balloon, typically being attached directly to an outer surface of the balloon. The scoring elements will be relatively short, typically having lengths below about 25% of the balloon length, preferably having lengths in the range from 2% to 10% of the balloon length. The relatively short, segmented scoring elements will permit highly flexible assemblies of balloon and scoring elements, generally meeting the flexibility requirement set forth above. The scoring elements may be arranged randomly over the balloon but will more usually be distributed uniformly over the balloon. In specific embodiments, the scoring elements may be arranged in helical, serpentine, or other regular patterns which circumscribe the balloon. As the balloon expands, such short segments will generally move apart from each other, but will still impart the desired scoring patterns into the vascular wall as the balloon is inflated.

In a fifth embodiment, the scoring catheter according to the present invention comprises a catheter body and a radially expandable balloon generally as set forth above. The balloon has a plurality of lobes extending between ends of the balloons, and at least one scoring element will be formed on at least one of the lobes in a manner arranged to score stenotic material as the balloon is expanded. The lobe will usually be in a helical pattern, and typically two, three, or more lobes will be provided. In the case of helical lobes, the scoring element(s) will usually be disposed along a helical peak defined by the helical lobe when the balloon is inflated. Such

helical scoring elements will be arranged to accommodate balloon inflation, typically being stretchable, segmented, or the like.

In still another aspect of the apparatus of the present invention, an expandable scoring cage is adapted to be carried over a balloon of a balloon catheter. The scoring cage comprises an assembly of one or more elongate elastic scoring elements arranged in a non-axial pattern. As defined above, the non-axial pattern may comprise both axial and non-axial segments. The assembly is normally in a radially collapsed configuration and is expandable over a balloon to a radially expanded configuration. After the balloon is deflated, the assembly returns to a radially collapsed configuration, preferably being assisted by the elastic nature of the scoring cage. Advantageously, the scoring cage will enhance uniform expansion of the underlying balloon or other expandable shell and will inhibit "dog boning" where an angioplasty balloon tends to over inflate at each end, increasing the risk of vessel dissection. The scoring elements will be adapted to score hardened stenotic material, such as plaque or fibrotic material, when expanded by the balloon in a blood vessel lumen. The scoring cage may be adapted to mount over the balloon with either or both ends affixed to the balloon, generally as described above in connection with prior embodiments. Preferred geometries for the scoring elements include those which circumscribe the balloon, those which are arranged helically over the balloon, those which are arranged in a serpentine pattern over balloon and the like.

In yet another aspect of the present invention, a method for dilatating a stenosed region in a blood vessel comprises radially expanding a shell which carries a scoring structure. The scoring structure scores and dilates the stenosed region and includes one or more non-axial scoring elements arranged to impart a circumscribing score pattern about the inner wall of the blood vessel as the shell is expanded. The stenosed region is typically characterized by the presence of calcified plaque, fibrotic plaque, or other hardened stenotic material which is preferably scored prior to dilatation. Preferably, the scoring structure will not be moved in an axial direction while engaged against the stenosed region, and the scoring structure may optionally be free from axially scoring elements.

In still another aspect of the present invention, an angioplasty catheter comprises a catheter body and a radially expandable shell near the distal end of the catheter body. An external structure, such as a scoring structure or cutting structure, is carried over but unattached to the shell. The catheter further comprises an attachment structure having a proximal end and a distal end attached to the scoring structure, wherein the attachment structure is sufficiently sized and compliant to accommodate reaction forces or geometrical changes produced by the scoring structure as it is expanded by the shell. Generally, at least a portion of said scoring structure is arranged helically over the shell. However, the scoring structure may comprise numerous different configurations as described above.

In one aspect of the present invention, the proximal end of the attachment structure is fixed to the catheter body and the distal end of the attachment structure is secured to the proximal end of the scoring structure. In all cases, the attachment structure is capable axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In a preferred embodiment, the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body. The inner diameter of the compliance tube is generally larger than an outer diameter of the catheter body so that the compliance tube freely extends and/or rotates with respect to the catheter body as the scoring structure foreshortens.

The compliance tube may also be sized to control the compliance of the scoring structure and expandable shell. Generally, the compliance tube has wall thickness ranging from 0.001 in to 0.1 in., preferably 0.005 in. to 0.05 in. The wall thickness may be increased to lessen the compliance of the system, or decreased to create a greater compliance. The length of the compliance tube may also be adjusted to control the compliance of the system. Generally, the compliance tube has a length ranging from 1 cm to 10 cm, but may range up to 30 cm or more for embodiments wherein the tube extends across the length of the catheter body.

In most cases, the material of the compliance tube may also be selected to control the compliance of the scoring structure and expandable shell. Generally, the compliance tube comprises an elastic material, preferably a polymer such as nylon or Pebax™. Alternatively, the compliance tube may comprise a braided material, metal or wire mesh.

In some aspects of the present invention, the compliance tube may have one or more perforations to control the compliance of the scoring structure and expandable shell. Generally, the perforations comprise one or more slots extending along the outside circumference of the compliance tube. The slots may form a pattern along the outside circumference of the compliance tube. The slots may be parallel to each other and/or extend helically or radially across the circumference of the compliance tube. The slots themselves may be formed of a variety of shapes, such as circular or rectangular.

Preferably, the compliance tube has an outer diameter that tapers from its distal end to its proximal end so that the outside diameter at the proximal end is slightly larger than the inner diameter, and the outside diameter at the distal end is sized to approximate the diameter of the scoring structure when in a collapsed configuration. This allows for the catheter to be readily removed from a vessel without catching or snagging on the vessel wall. For the tapered configuration, the outer diameter of the compliance tube will vary depending on the size of the catheter body and the expansion cage, but the diameter generally tapers down in the range of 0.004 in. to 0.010 in. from the distal end to the proximal end.

In another aspect of the invention, the attachment structure is connected at its distal end to the scoring structure and at its proximal end to a manipulator. Typically, the manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the scoring structure across the length of the catheter body. In all cases, the attachment structure is capable of axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In a preferred embodiment, the attachment structure comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body. Typically, the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely extends and rotates with respect to the catheter body as the scoring structure foreshortens. The compliance of the scoring structure and expandable shell may be controlled by adjusting the thickness, length, or material selection of the compliance tube.

In some embodiments, the compliance of the scoring structure is controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. Specifically, the attachment structure may be axially advanced with respect to the catheter body as the balloon is being inflated or deflated. For example, the attachment structure may be pulled away from the distal end of the catheter body while the

balloon is being expanded to constrain the compliance of the balloon. Alternatively, the manipulator may be used to rotate the attachment structure with respect to the catheter body to control the compliance of the balloon during transition.

In another embodiment of the present invention, a method of dilatating a stenosed region in a blood vessel comprises introducing a scoring structure carried over an expandable shell that is connected to a catheter body by an attachment structure, and expanding the scoring structure within a stenosed region within the blood vessel. In this method, the attachment structure axially and/or rotationally extends to accommodate foreshortening of the scoring structure as the shell is expanded. The attachment structure generally comprises a compliance tube having an outer diameter and an inner diameter that extends over the catheter body, wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely extends and rotates with respect to the catheter body as the scoring structure foreshortens. The thickness, length, and material of the compliance tube may be selected to control the compliance of the scoring structure and expandable shell.

In some embodiments, the method further comprises the step of fixing the proximal end of the attachment structure to the catheter body. Alternatively, the method may comprise the step of fixing the proximal end of the attachment structure to a manipulator. In such an embodiment, the manipulator is positioned at the proximal end of the catheter body and the attachment structure extends from the scoring structure across the length of the catheter body. This allows for the compliance of the scoring structure and balloon to be controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. Actuation of the manipulator may occur by axially advancing, pulling, or rotating the attachment structure with respect to the catheter body.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**, **1**A, **1**B, and **1**C are schematic illustrations of the balloon scoring structure embodiment in accordance with an embodiment of the invention.

FIG. **2** is a schematic illustration of an exemplary helical scoring structure embodiment in accordance with embodiments of the invention.

FIG. **3** is a schematic illustration of an expanded angioplasty balloon carrying a helical scoring structure in accordance with embodiments of the invention.

FIG. **4** illustrates a scoring structure comprising an alternating serpentine pattern of intermediate scoring elements between a pair of end collars.

FIG. **5** illustrates the serpentine scoring elements of the embodiment of FIG. **4** shown in a rolled-out configuration.

FIG. **6** illustrates a scoring structure comprising alternating C-shaped scoring elements between a pair of end collars.

FIG. **7** illustrates the C-shaped scoring elements of the embodiment of FIG. **6** shown in a rolled-out configuration.

FIG. **8** is a view of one of the C-shaped scoring elements taken along line **8**-**8** of FIG. **6**.

FIG. **9** illustrates an alternative double C-shaped scoring element which could be utilized on a scoring structure similar to that illustrated in FIG. **6**.

FIG. **10** illustrates an alternative embodiment of a helical scoring structure comprising serpentine and zigzag structures for mounting onto a balloon catheter.

FIG. **11** illustrates a first of the serpentine mounting elements of the scoring structure of FIG. **10**.

FIG. **12** illustrates a second of the serpentine mounting elements of the scoring structure of FIG. **10**.

FIG. **13** illustrates an alternative mounting structure for a helical or other scoring structure.

FIG. **14** illustrates the mounting structure of FIG. **13** shown in a rolled-out configuration.

FIG. **15** shows yet another embodiment of a mounting element for the scoring structures of the present invention.

FIG. **16** illustrates the mounting structure of FIG. **15** shown in a rolled-out configuration.

FIG. **17***a* illustrates yet another alternative embodiment of a catheter constructed in accordance with the principles of the present invention, where an attachment structure is disposed between the scoring structure and the catheter body.

FIG. **17***b* illustrates the structure of FIG. **17***a* shown without the balloon.

FIGS. **18***a-c* illustrate a catheter constructed in accordance with the principles of the present invention having an attachment structure with various patterned perforations.

FIG. **19** illustrates another embodiment of a catheter constructed in accordance with the principles of the present invention having a tapered attachment structure.

FIG. **20** illustrates yet another alternative embodiment of a catheter constructed in accordance with the principles of the present invention, where an attachment structure is connected to a manipulator.

FIG. **21** illustrates an embodiment of the invention having a laminated section at the distal end of the compliance tube.

FIG. **22** illustrates another view of the embodiment of FIG. **21**.

FIG. **23** illustrates the embodiment of FIG. **21** with an expandable balloon inserted within the scoring structure.

FIG. **24** illustrates an embodiment with a sleeve over the distal end of the scoring structure.

FIG. **25** illustrates a method of the present invention utilizing an insertion tube to mount the scoring structure over the expandable balloon.

FIG. **26** illustrates shows the insertion tube inserted over the expandable balloon.

FIG. **27** illustrates a scoring catheter of the present invention with the insertion tube removed.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well-known features may be omitted or simplified in order not to obscure the present invention.

Embodiments of the present invention relate to device for revascularization of stenotic vessels and specifically to a balloon catheter having external elements. The dilatation device comprises a conventional dilatation balloon such as a polymeric balloon and a spiral, or external elements with other configurations mounted on the balloon catheter.

Reference is now made to FIGS. **1**, **1**A, and **1**B, which are schematic illustrations of a dilatation device **10** in accordance with embodiments of the invention. The dilatation device **10** includes a dilatation balloon **12**, which may be any conventional angioplasty balloon such as commonly used by interventional cardiologists or radiologists, and a helical or spiral unit **14** mounted over or attached to dilatation balloon **12**. The compliance of the balloon and the scoring element(s) should

be chosen to assure uniform expansion of the balloon substantially free from "dog-boning" as the combined structure expands within a lesion. If a compliant or a semi-compliant balloon is used and the compliance of the scoring element was not matched to comply with the properties of the balloon, the expansion of the balloon-scoring element system will not be uniform. This non-uniformity may impair the efficacy of the scoring catheter and, in some cases, may result in poor performance. For example, under given pressure, certain parts of the balloon will be able to expand while other parts will be constrained by excessive resistance of the scoring elements.

Helical unit **14** is typically made of nitinol. Helical unit **14** may be made of other metals such stainless steel, cobalt-chromium alloy, titanium, and the like. Alternatively, spiral unit **14** may be a polymeric spiral, or made of another elastic material. Helical unit **14** may be attached at its proximal and distal ends to the proximal end **17** and distal end **18** of dilatation balloon **12**. Alternatively, spiral unit **14** may be attached to the distal end and/or the proximal end of dilatation balloon **12** by collar-like attachment elements **15** and **16**. Spring or other compliant elements may be alternatively or additionally provided as part of the attachment elements to accommodate shortening of the helical unit as it is expanded.

Dilatation device **10** is inserted into the vascular system, for example, using a conventional catheter procedure, to a region of stenotic material **22** of blood vessel **20**. (The term "stenotic" is used herein to refer to the vascular lesion, e.g., the narrowed portion of the vessel that the balloon is meant to open.) At the stenotic area, the dilatation balloon **12** is inflated, for example, by liquid flow into the balloon. Helical unit **14** widens on the inflated dilatation balloon **12**. On inflation, the dilatation balloon **12** together with the helical unit **14** is pressed against the walls of blood vessel **20** as shown in FIG. **1**B.

Reference is now made to FIG. **1**C, illustrating blood vessel **20** after the deflation of dilatation balloon **12**. Helical unit **14** narrows when deflating the dilatation balloon **12**, thus the dilatation device **10** is narrowed and may be readily retrieved from blood vessel **20**. The deflation profile of the balloon **10** is low and mainly circular. The stenotic material **22** in blood vessel **20** is pressed against blood vessel **20** walls to widen the available lumen and enhance blood flow. The pressing of helical unit **14** against the walls of blood vessel **20** causes scoring **23** in the stenotic area.

Reference is now made to FIG. **3** that shows a scoring structure in the form of a single wire **24** wrapped around a dilatation balloon **12** in a helical configuration.

In other embodiments, the scoring structure of the present invention can have a non-helical configuration. Any design of scoring structure that can accommodate an increase in the diameter of the balloon **12** upon inflation, and return to its configuration when the balloon is deflated, is an appropriate design useful in the invention. At least a portion of the scoring elements will not be parallel to the longitudinal axis of the balloon catheter to enhance flexibility and improve scoring.

Referring again to FIGS. **1**A-**1**C, helical unit **14** is pushed outwardly by the inflation of the balloon **12**, and is stretched by the inflation of the balloon. When the balloon is deflated, helical unit **14** assists in the deflation by its elastic recoil. This active deflation is faster and also leads to a low profile of the deflated balloon. The balloon **12** is disposed within the helical unit **14**, which returns to its pre-inflated shape and forces the balloon to gain a low radial profile.

In another embodiment of the invention, dilatation device **10** may carry a stent. The stent can be crimped over the helical unit **14**. In this way, the helical unit **14** can push the stent against hard areas of the lesion, enabling proper positioning of the stent against the vessel wall, even in hard-calcified lesions without pre-dilation.

Reference is now made to FIG. **2**, illustrating the helical unit **14** in accordance with embodiments of the invention. Helical unit **14** is typically made of nitinol. Helical unit **14** includes three wires **19** that are attached to collars **15** and **16** at the proximal end and distal end, respectively. Alternatively the scoring structure may be formed as a metallic cage, which can be made from a slotted tube, or polymeric cage or polymeric external elements. Alternatively, the scoring structure may comprise wires of other elements attached directly to the balloon material or close to the balloon ends.

Wires **19** (FIG. **2**) are attached between collars **15** and **16**. The diameter of the wires is typically in the range of 0.05 mm to 0.5 mm. Alternatively, a cage (for example a metallic cage made of a slotted tube) can be used in several configurations that allow local stress concentrations. The size and shape of the cross section of the cage elements or the cross section of the wires can vary. The cross section can be a circle, rectangle, triangle, or other shape.

In alternative embodiments, the wires **19** may comprise short segments that are attached to the balloon **12**.

In further alternative embodiments of the invention, the helical unit **14** may be glued, thermally bonded, fused, or mechanically attached at one or both ends to dilatation balloon **12**.

In yet another embodiment, a scoring structure may comprise wires that are attached to the dilatation balloon **12** in a helical configuration or other configuration. The wires may be thermally attached to the balloon **12**, glued, mechanically attached, or the like.

In still another embodiment, a scoring structure comprises wire or cage elements that are not parallel to the longitudinal axis of the balloon **12** so that the combination of the scoring structure **19** and the balloon **12** remains flexible.

In additional embodiments, the combination of dilatation balloon **12** and scoring structure scores the lesion and provides better vessel preparation for drug eluting stents by allowing better positioning of the stent against the vessel wall and diffusion of the drug through the scores in the lesion.

In these embodiments, the balloon can be used as a platform to carry drugs to the lesion where scoring of the lesion can enhance delivery of the drug to the vessel wall.

In these embodiments, the balloon can be used for a local drug delivery by embedding drug capsules, drug containing polymer, and the like, through the stenotic material and into the vessel wall.

From the above, it can be seen that the invention comprises catheters and scoring structures, where the scoring structures are positioned over the balloons or other expandable shells of the catheter. The scoring structures may be attached directly to the balloons or other shells, in some cases being embedded in the balloon material, but will more usually be formed as separate cage structures which are positioned over the balloon and attached to the catheter through attachment elements on either side of the balloon. The expandable cages may be formed using conventional medical device fabrication techniques, such as those used for fabricating stents, such as laser cutting of hypotube and other tubular structures, EDM forming of hypotubes and tubes, welding of wires and other components and the like.

Typically, such expandable shell structures will comprise the attachment elements and an intermediate scoring section between the attachment elements. As illustrated in the embodiments above, the attachment elements may be simple cylindrical or tube structures which circumscribe the catheter body on either side of the balloon or other expandable shell.

The simple tube structures may float over the catheter body, i.e., be unattached, or may be fixed to the catheter body. A number of alternative embodiments for the attachment elements will be described in connection with the embodiments below.

The intermediate scoring sections may also have a variety of configurations where at least some of the scoring elements will typically be disposed in a non-axial configuration, i.e., in a direction which is not parallel to the axial direction of the expandable cage. A preferred configuration for the intermediate scoring section comprises one or more helical elements, generally as illustrated in the prior embodiments. Other exemplary configurations are set forth in the embodiments described below.

Referring now in particular to FIGS. **4** and **5**, an expandable scoring cage **100** comprises first and second attachment elements **102** and **104**, respectively, and an intermediate scoring section **106** comprising a plurality of curved serpentine members **110**. The serpentine members **110** extend circumferentially in opposite directions in an alternating manner. This can be understood by observing a "rolled-out" view of the serpentine elements as illustrated in FIG. **5**. A second alternative scoring cage structure **120** is illustrated in FIGS. **6-8**. The scoring cage **120** comprises first and second attachment elements **122** and **124** joined by a spine **126**. A plurality of C-shaped scoring elements **128** and **130** are attached to the spine and extend in opposite circumferential directions. The shape of the element can be observed in FIG. **8**. The opposite directions may be observed in the rolled-out view of FIG. **7**.

It will be appreciated that a variety of different circumferential structures may be used in place of the C-shaped structures of FIGS. **6-8**. For example, a pair of opposed C-shaped partial ring structures may be utilized, as illustrated in FIG. **9**. The C-shaped structures of FIG. **6** or the double C-shaped structures of FIG. **9** can also be extended so that they wrap around a balloon more than one time, either over or under the spine structure **126**.

The expandable cage structures **100** and **120** will each be mounted over a dilatation balloon, such as the balloon of FIGS. **1-3**, with the attachment elements secured to the catheter body on either side of the dilatation balloon. The tube or cylindrical attachment elements **102**, **104**, **122**, and **124** may simply float over the catheter body. In other embodiments, however, it may be desirable to use an adhesive or other means for affixing either one or both of the attachment elements to the catheter body. Having at least one floating attachment element, however, is often desirable since it can accommodate shortening of the intermediate scoring section as that section radially expands. In other cases, however, the individual scoring elements may possess sufficient elasticity to accommodate such shortening. For example, nitinol and other shape memory alloys possess significant stretchability, typically on the order of 8%, which in some instances will be sufficient to accommodate any tension applied on the intermediate scoring section by radial expansion of the balloon.

Referring now to FIGS. **10-12**, alternative attachment elements are shown on an embodiment of an expandable scoring cage **140** comprising three helical scoring elements **142** which make up the intermediate scoring section. A first attachment element **146** comprises a single serpentine ring, as best illustrated in FIG. **11** while a second attachment element **148** comprises a pair of tandem serpentine rings **150** and **152**, as best illustrated in FIG. **12**. The use of such serpentine attachment structures is beneficial since it permits crimping of either or both of the structures onto the catheter body in order to fix either or both ends of the structure thereto. Usually, the single serpentine attachment structure **146** will be affixed to the catheter body while the double serpentine structure will be left free to allow movement of that end of the scoring cage to accommodate radial expansion of the underlying balloon.

Referring now to FIGS. **13** and **14**, a further alternative embodiment of an attachment element useful in the scoring cages of the present invention is illustrated. Attachment element **180** includes a pair of serpentine rings **182** and **184**, generally as shown in FIG. **13**, in combination with a coil spring structure **186** located between said rings **182** and **184**. The coil spring structure **186** includes three nested coil springs **190**, each joining one of the bend structures **192** and **194** on the serpentine rings **182** and **184**, respectively. The structure of the spring structure and adjacent serpentine rings can be understood with reference to the rolled-out configuration shown in FIG. **14**.

The attachment structure **180** is advantageous since it permits a fixed attachment of the outermost ring **182** to the underlying catheter body while the inner ring **184** remains floating and expansion and contraction of the intermediate scoring section, comprising helical elements **196**, is accommodated by the coil spring structure **186**. Since the scoring cage is fixed to the catheter, any risk of loss or slippage from the balloon is reduced while sufficient compliance is provided to easily accommodate radial expansion of the intermediate scoring section. By attaching the structures **180** at at least one, and preferably both ends of the scoring cage, the risk of interference with a stent is reduced.

In some embodiments, collars, such as those shown in FIGS. **1** and **2**, or attachment elements, such as those shown in FIGS. **10-12**, may comprise a flexible material that allows the collar or attachment element to expand while being mounted over the balloon catheter and then be collapsed to the diameter of the catheter. The expandability of the collars and/or attachment elements may be achieved by a compliant memory material such as nitinol or a polymer, or by use of a flexible serpentine design as shown in FIGS. **10-12**. Where collars are used, the collar may be shaped or have a slit down the circumference (not shown) so that the collar may be expanded during mounting over the balloon. Alternatively, the collar may be oversized to accommodate the balloon diameter mounting, and then crimped down to secure the secure the scoring structure to the catheter body.

Yet another embodiment of the attachment element of the present invention includes an axial spring as shown in FIGS. **15** and **16**. The attachment element **200** includes a terminal serpentine ring **202** and an intermediate spring structure **204** including a number of axial serpentine spring elements **206**. The nature of the serpentine ring elements **206** can be observed in the rolled-out configuration of FIG. **16**. Optionally, a second serpentine ring **210** may be provided between the attachment structure **200** and the helical scoring elements of the intermediate scoring section **212**.

The embodiments of FIGS. **13-16** comprise spring-like elements **186** and **204** to accommodate axial shortening of the scoring structure upon radial expansion. It will be appreciated that other metal and non-metal axially extensible structures could also be used in such attachment structures. For example, elastic polymeric tubes could be attached at one end to the scoring structures and at another end to the catheter body (or to a ring, collar or other structure which in turn is fixed to the catheter body).

Referring now to FIGS. **17***a* and **17***b*, a further embodiment of an angioplasty catheter **250** having an axially distensible attachment structure **258** is illustrated. External structure **252** is held over expandable dilatation balloon **254** and is fixed at

one end to the distal end **260** of catheter body **256**. The external structure may comprise any structure typically used for removal of plaque/thrombus from a vessel wall such as a scoring structure, cutting structure, or crushing structure. The proximal end **262** of external structure **252** is connected to the distal end **264** of attachment structure **258**. The proximal end **266** of attachment structure **258** is fixed to the catheter body **256**. As described below, the attachment structure **258** may be configured to reduce forces applied on the external structure **252** and the catheter body **256** during expansion and contraction of balloon **254**.

In a preferred embodiment, attachment structure **258** comprises a cylindrical over-tube, or compliance tube, made of an elastic material. Over-tube **258** generally has an inner diameter that is slightly greater than the outer diameter of the catheter body **256**. Because only a small section of the proximal end of the attachment structure **258** is fixed to the catheter body, the distal end **264** attached to external structure **252** is free floating, and is free to slide axially and rotationally with respect to catheter body **256**. Attachment structure **252** may be fixed, for example by adhesion, directly to the to catheter body **256** and external structure **252**, or to a collar or other intermediate attachment means.

As balloon **254** is expanded, external structure **252** expands in circumference and contracts axially along the catheter body **256**, creating axial force A on attachment structure **258**. Attachment structure **258**, fixed to the catheter at its end **266**, axially stretches to accommodate the axial movement of the external structure **252**. External structure **252** also tends to rotate about the catheter body **256**, causing a torsional force T. The distal end **264** of attachment structure **258** rotates through the full range of motion of scoring structure **252** to accommodate torsional force T, while proximal end **266** remains stationary with respect to catheter body **256**.

The configuration illustrated in FIGS. **17***a* and **17***b* allows the compliance of the expandable system to be controlled. Generally, where one end of the scoring structure is free, the compliance of the expandable system will be a combination of the compliance of the balloon and the scoring structure. However, because the ends of the expandable system shown in FIG. **17** are fixed at distal end **260** and proximal end **266**, the attachment structure controls the compliance of the expandable system.

The compliance of the system may be varied by any combination of material selection, wall thickness, or length of the over-tube **258**. Over-tube **258** may comprise any elastomer, such as elastic polymer like Nylon, Pebax, or PET. Typically, compliance tube **258** is formed from extruded tubing, but it may also comprise braided polymeric or metallic fibers, or wire mesh. A high memory metal such as nitinol or stainless steel may also be used. Where the compliance tube comprises an extruded polymeric tube, the wall thickness can vary in the ranges set forth above, and the length of the tube can range from 1 cm to 10 cm. For the same material, the thinner-walled and longer the tube, the more compliant the system.

Referring to FIGS. **18***a-c*, the compliance of angioplasty catheter **300** may also be varied by creating one or more perforations in compliance tube **258**. The perforations may comprise one or more slots in the circumference of the tubing. The slots may comprise one continuous slot spiraling across the length of compliance tube **258**, or may be a number of slots aligned in any number of patterns, such as helical **312** or radial **314**. The slots may also be any number of shapes, such as circular or rectangular, and may have a discreet length or be contiguous across the surface of the compliance tube.

Referring to FIG. **19**, the outside diameter of compliance tube **258** may be tapered to facilitate delivery and retrieval of the scoring catheter **320** from the treatment site within the lumen. Generally, the outer diameter will be larger at the distal end **264** of the compliance tube **258** and smaller at the proximal end **266** of the compliance tube. The outside diameter D_1 at the distal end will vary depending on the profile of the scoring structure and balloon when collapsed but typically range from 0.004 in. to 0.01 in. larger than the outside diameter D_2 at the proximal end. The outside diameter D_2 at the proximal end is generally as close as possible to the outside diameter of the catheter body to create a smooth transition between the compliance tube and the catheter. As an example, for a catheter body having an outside diameter of 0.033 in., outside diameter D_1 at the distal end may be 0.042 in. with an inner diameter of 0.038 in., the inner diameter providing clearance between the catheter body so that the distal end of the compliance tube can move relative to the catheter body. Correspondingly, the outside diameter D_2 at the proximal end may taper down to 0.0345 in., with an inner diameter of 0.034 in. to closely match the catheter body having outside diameter with enough clearance to be bonded to the catheter body by an adhesive.

The taper may run across the whole length of the compliance tube, or alternatively be only tapered at a section of the length of the compliance tube. The tapered compliance tube **258** smoothes the transition between the scoring structure and catheter body, and minimizes the likelihood of the outer tube or scoring structure snagging or catching on a portion of the luminal wall during delivery or retrieval of the catheter.

Now referring to FIG. **20**, an alternative embodiment of a scoring catheter **350** is shown having a manipulator **360**. The attachment structure **258** is connected at its distal end **264** to the scoring structure **252**. Instead of being secured directly to the catheter body **256**, the proximal end **266** is attached to manipulator **360**. Typically, the manipulator **360** is positioned at the proximal end of the catheter body **256** and the attachment structure **258** extends from the scoring structure across the length of the catheter body. Like the above embodiments, the attachment structure is capable of axially and rotationally extending to accommodate foreshortening of the scoring structure as the shell is expanded.

In some embodiments, the compliance of the scoring structure **252** and balloon **254** is controlled by actuating the manipulator during expansion or contraction of the radially expandable shell. In one aspect, the attachment structure **258** may be axially advanced with respect to the catheter body **256** as the balloon is being inflated or deflated. For example, the attachment structure **258** may be pulled away from the distal end of the catheter body **256** while the balloon **254** is being expanded to constrain the compliance of balloon. The attachment structure **258** may also be pulled away from the distal end of the catheter body **256** during or after the balloon **254** is being deflated to minimize the profile of the balloon and scoring structure. Alternatively, the manipulator **360** may be used to rotate the attachment structure **258** with respect to the catheter body **256** to control the compliance of the balloon and scoring structure during transition from a collapsed to expanded state and back to a collapsed state.

Now referring to FIGS. **21** and **22**, a scoring cage structure **400** is illustrated having a two-layer laminated compliance tube **402**. As shown in FIG. **22**, the compliance tube **402** has a laminated structure **404** at at least its distal end **410**. The laminated structure holds the proximal ends **408** of the scoring elements **406** as shown in broken line in FIG. **22**. The scoring elements **406** may be sized to fit over the outside of the compliance tube **402**, as illustrated in FIG. **22**, with the lamination covering the elements. Alternatively, the compli-

ance sleeve tube **402** may be sized to fit inside of the scoring structure **406**, with the laminating layer(s) formed over the elements **406** (not shown).

The laminating structure may be composed of a polymer similar to the compliance tube **402**, and may be heat shrunk or melted to thermally bond the compliance sleeve to the compliance tube and sandwich the scoring structure **406**. Alternatively, an adhesive or other bonding method such as ultrasonic or RF energy may be used to laminate the structure. The laminated structure, as shown in FIGS. **21** and **22**, provides a smoothed transition and strengthened bond between the scoring cage and the attachment structure. Such a smooth transition is a particular advantage when withdrawing the scoring cage from the vasculature.

FIGS. **23** and **24** illustrate scoring cage **400** positioned over an expandable dilation balloon **412**. As shown in FIG. **24**, distal end **418** of the scoring structure may be coupled to the distal tip **414** of the catheter body by an end cap **416**. The end cap **416** may be composed of a compatible polymer and thermally bonded with the catheter body to fix distal end **418** of the scoring structure to the catheter body.

Now referring to FIGS. **25-27**, a method is illustrated for mounting an expandable scoring cage **406** over a balloon catheter. The scoring cage **406** is pre-expanded by loading it over an insertion tube **422** that has an inner diameter slightly larger than the outer diameter of the balloon **412**. A catheter body **420** having a balloon **412** is then inserted into the inner diameter of the insertion tube **422** and advanced until the balloon **412** is appropriately positioned with respect to the scoring structure **406**, as illustrated in FIG. **26**. The insertion tube **422** is then pulled back to allow the expanded scoring structure to collapse over the balloon **412** and the catheter body **420**, as shown in FIG. **27**. The scoring structure **406** may then be secured at its distal end **418** to the distal tip **414** of the catheter body **420** and the proximal end **424** of the scoring structure/attachment structure assembly to a medial location on the catheter body **420**.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Alternate embodiments are contemplated that fall within the scope of the invention.

What is claimed is:

1. A method of dilating a stenosed region in a blood vessel, the method comprising:

introducing an external structure having a distal end and a proximal end carried over an expandable shell, wherein the external structure is unattached to the shell, the distal end is fixedly attached to a catheter body, and the proximal end is connected to the catheter body by an attachment structure; and

expanding the expandable shell to dilate external structure within the stenosed region within the blood vessel, wherein the proximal end of the external structure moves distally and the attachment structure axially lengthens to accommodate such distal movement of the external structure as the shell is expanded, wherein the attachment structure comprises a compliance tube having one or more perforations to enhance compliance; wherein the inner diameter of the compliance tube is larger than an outer diameter of the catheter body so that the compliance tube freely lengthens and rotates with respect to the catheter body as the external structure foreshortens.

2. The method as in claim **1**, wherein the attachment structure further accommodates rotation of the external structure as the shell is expanded.

3. The method as in claim **1**, wherein the compliance tube comprises an elastic material.

4. The method as in claim **3**, wherein the compliance tube comprises a polymer.

5. The method as in claim **3**, wherein the compliance tube comprises a metal.

6. The method as in claim **1**, wherein the perforations in the tubular body comprise slots.

7. The method as in claim **6**, wherein the slot is formed as a continuous spiral.

8. The method as in claim **1**, wherein the one or more perforations comprise one or more slots extending along the outside circumference of the compliance tube.

9. The method as in claim **8**, wherein the slots form a pattern along the outside circumference of the compliance tube.

10. The method as in claim **9**, wherein the slots are parallel to each other.

* * * * *

United States Court of Appeals
for the Federal Circuit

Trireme Medical, LLC v. Angioscore, Inc., No. 2015-1504

CERTIFICATE OF SERVICE

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by ARNOLD & PORTER, LLP, Attorneys for Appellant to print this document. I am an employee of Counsel Press.

On **May 29, 2015,** counsel has authorized me to electronically file the foregoing **Opening Brief for Appellant** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

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Paper copies will also be mailed to the above principal counsel at the time paper copies are sent to the Court.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court within the time provided in the Court's rules.

May 29, 2015

/s/ Elissa Matias
Counsel Press

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 9,307 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in Times New Roman 14 point font.

DATED: May 29, 2015.

Respectfully,

By */s/ David A. Caine*
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